File No: LTD/1633

December 2012

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Jeffamine Uniprime Adduct

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1633	PPG Industries Australia Pty Ltd	Polymer in Jeffamine Uniprime Adduct	ND*	< 500 tonnes per annum	Component of OEM automotive coatings

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As only limited toxicity data were available, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The environmental hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute (Category 2)	H401 - Toxic to aquatic life

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

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced in the solution and as diluted for use in the automotive coating products:
  - Adequate local exhaust ventilation, where aerosols or mists may be formed

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced in the solutions and as diluted for use in the automotive coating products:
  - Chemical resistant gloves
  - Coveralls
  - Chemical goggles
  - Respiratory protection, if inhalation exposure may occur

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills 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 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 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 1,000

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from being a component of automotive OEM coatings, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 500 tonnes per annum, or is likely to increase significantly;
  - 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 (M)SDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

This notification has been carried out under the approved foreign scheme provisions (Canada) of Section 44 of the Act. The health and environment hazard assessment of the Canadian report was provided to NICNAS and where appropriate used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemical were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
PPG Industries Australia Pty Ltd (ABN: 82 055 500 939)

Mc Naughton Road
CLAYTON VIC 3168

NOTIFICATION CATEGORY
Limited (Foreign Scheme Notification): Synthetic polymer with Mn ≥ 1,000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, import volume, and identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: water solubility, hydrolysis as a function of pH, partition co-efficient, absorption/desorption and dissociation constant.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (1997), USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Jeffamine Uniprime Adduct (product containing the notified polymer)

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference FTIR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Liquid (product containing approximately 5% of the notified polymer)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Imported in aqueous solution
Boiling Point	100°C*	(M)SDS of the product
Relative Density	1.03*	(M)SDS of the product
Vapour Pressure	2.3 kPa at 20 °C*	(M)SDS of the product
Water Solubility	Not determined	Solubility test results, measured by visual inspection (0.156 - 0.189 g/L), were unreliable because undissolved test material could not be separated from saturated solution by centrifugation and/or filtration. The notified polymer is expected to be dispersible in water based on its use in aqueous products.
Hydrolysis as a Function of pH	Not determined	The notified polymer contains no hydrolysable groups and is expected to be stable under environmental conditions
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer has a potential to partition to organic phases based on its high n-octanol solubility and limited water solubility.
Adsorption/Desorption	Not determined	The notified polymer is expected to adsorb to soil, sediment and sludge based on its high molecular weight and the presence of potentially cationic functional groups.

Dissociation Constant	Not determined	The notified polymer is a salt and will be ionised under environmental conditions.
n-Octanol solubility	3.66 g/L at 20 °C	Measured for an analogue of the notified polymer in accordance with modified OECD TG 105, shake flask method
Particle Size	Not determined	Imported in aqueous solution
Flash Point	93.89°C*	(M)SDS of the product (closed cup method)
Flammability	Not determined	Imported in aqueous solution
Autoignition Temperature	Not determined	Imported in aqueous solution
Explosive Properties	Not determined	The notified polymer contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined	The notified polymer contains no functional groups that would imply oxidative properties.

*Characteristics of the product containing the notified polymer

DISCUSSION OF PROPERTIES

Reactivity
The notified polymer is expected to be stable under normal conditions of use.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported in a solution at a concentration up to approximately 5%. In future, there is a possibility for the notified polymer to be imported at a higher concentration and reformulated in Australia.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 500	< 500	< 500	< 500	< 500

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
PPG Industries Australia Pty Ltd, automotive manufacturers and industrial coating operations

TRANSPORTATION AND PACKAGING
The notified polymer will be imported into Australia as a solution at a concentration up to approximately 5%, packaged in bulk ISO containers or 200 L steel drums. The solution containing the notified polymer will be transported from dockside to a warehouse and then distributed to end-users by road.

USE
The notified polymer will be used as a component of automotive metal coatings for motor vehicles and parts.

OPERATION DESCRIPTION

Coating Formulation
Where formulation occurs in Australia, the imported solution containing the notified polymer at up to approximately 5% will be pumped into a holding tank. Following mixing with other ingredients, a sample of the formulated coating mix containing less than 3% of the notified polymer will be removed for quality control purposes. The formulated coating mix will then be filtered, filled into 200 L drums and stored in a warehouse prior to distribution to automotive manufacturers in Victoria.

Coating Application
At the end-use site, the formulated coating mix (either as imported or formulated in Australia) will be pumped into a large epoxy-lined steel tank. A sample may be removed for quality control purposes. Metal parts of car bodies to be coated will be lowered into the tank from an overhead conveyor and an electric current will be applied, in order to bind the coating to the metal surface. After the electrocoating process, the vehicle metal parts will be carried by the overhead conveyors through a series of rinse stages either with water or diluted

paint solution to remove residual polymer not bound to the metal. At the final stage, the overhead conveyors will carry the coated metal parts to an oven for curing.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport workers	2	12
Warehouse staff	2	24
Production workers		
– Coating formulation	4	60
– Quality control	2	60
– Electrocoating process	8	120
– Cleaning	4	30
– Waste disposal	2	30

EXPOSURE DETAILS

Transport and storage
During transport and storage, workers are not expected to have exposure to the notified polymer under normal conditions unless a spill event occurs. In the case of spill, workers may have dermal, ocular or inhalation exposure to solutions containing the notified polymer at up to approximately 5%.

Coating Formulation
Dermal and ocular exposure to the notified polymer at concentration up to approximately 5% may occur during transfer, removal and testing of the polymer emulsion. Dermal and ocular exposure to the notified polymer at concentration up to 3% may also occur during formulation, packaging and transfer of the formulated coating mix, and during general cleaning and maintenance of the coating equipment. Inhalation of the vapour of the solutions containing the notified polymer may also occur. However, under normal conditions of operation, the exposure to the notified polymer through all routes would be limited by the expected use of exhaust ventilation and personal protection equipment (PPE), including coveralls, protective glasses and chemical resistant gloves.

Coating Application
Exposure to the notified polymer is likely to be low during the largely automated coating, rinsing and curing processes. Under normal conditions of operation, exposure to the notified polymer would also be reduced by use of the recommended PPE. Once the coatings are applied to the metal surfaces and cured, the notified polymer is expected to be bound within an inert matrix and will not be bioavailable for exposure.

6.1.2. Public Exposure
The notified polymer is intended for industrial use only and exposure of the general public is not expected. Once the coating processes are complete, the notified polymer will be cured into inert coatings on motor vehicles and automotive parts, and will not be bioavailable for exposure.

6.2. Human Health Effects Assessment

No toxicity data was provided for the notified polymer. The result from an acute oral toxicity study on a compound structurally similar to the notified polymer is summarised in the following table, and is indicative of low toxicity under the test conditions. For full details of the study, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity (gavage)	LD50 > 2,000 mg/kg bw; low toxicity

Toxicokinetics, metabolism and distribution.
The number average molecular weight (Mn) of the notified polymer is above 1,000 Da. Polymers of high

molecular weight are not expected to readily cross the skin or other biological membranes.

Acute toxicity.
According to the data provided for a polymer similar to the notified polymer, the acute oral toxicity of the notified polymer is assumed low with LD50 > 2,000 mg/kg bw. No studies on dermal or inhalation toxicity were provided by the notifier.

Irritation and sensitisation.
No skin irritation or sensitisation data were provided. Predicted from the structure, the notified polymer could be a skin and eye irritant, and may have sensitisation potential.

Health hazard classification
Based on the limited toxicity data available, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on limited toxicological data and the structure of the notified polymer, it is expected to have low acute oral toxicity, but may have potential for skin and eye irritation and skin sensitisation.

Coating reformulation/application operators and laboratory staff may come into contact with the solutions containing the notified polymer at up to approximately 5%. Exposure is expected to be limited during formulation/application by the engineering controls and PPE used, and the enclosed and automated processes. The relatively low concentration of the chemical in the product would also reduce exposure. After the coating has been applied and cured, the notifier polymer will be bound into an inert matrix of the metal coatings and will not be bioavailable for further exposure. Under the proposed occupational settings and control measures, the notified polymer is not considered to pose an unreasonable risk to workers.

6.3.2. Public Health
Members of the public may come into contact with surfaces coated with coating products containing the notified polymer. However, after the coatings are cured, the notified polymer will be bound into an inert matrix and will not be bioavailable for exposure. Based on very low exposure potential, the risk of the notified polymer to public health is not expected to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will be imported into Australia as a component of industrial coating for application in the automotive industry. Reformulation may occur locally in the future. It is estimated by the notifier that up to 1% of the total annual import volume of the notified polymer (due to sampling, maintenance and waste from the cleaning of equipment) may be released to the environment during coating reformulation processes. These wastes are expected to be collected and cured/concentrated for future disposal, which most likely entail landfill disposal.

RELEASE OF CHEMICAL FROM USE
The materials containing the notified polymer are currently only used in the automotive industry. The potential release scenarios of the notified polymer at the industrial coating plants include:

a) Road tanker delivery to plants
No significant release of the product containing the notified polymer is expected during transport. In the unlikely event of a spill, the product containing the notified polymer will either be contained and disposed to landfill or will be drained to the internal waste water treatment plant (WWTP).

b) Electrocoat (e-coat) immersion tank

Automotive bodies and parts are passed through the electrocoat tank by conveyor where the e-coating is deposited on the surface. The e-coat tank is replenished with additional coating. Overflow and excess coating is expected to be recycled or directed to internal WWTPs. Residues collected from filtration of the e-coat tank contents are also expected to be directed to internal WWTPs. It is expected the filters will eventually be dried and disposed to landfill. No significant release of the notified polymer is expected at this stage.

c) E-Coat wash water tanks
Rinsing of the automotive metal surfaces after deposition is conducted by a closed loop process, with successive rinses, each feeding back to the previous rinse. The final rinse drainings and filtration residues, containing a very small amount of the notified polymer, are expected to be directed to internal WWTPs. WWTPs sludge, containing residues of the notified polymer, is expected to be disposed of to landfill, and effluent is expected to be directed to local sewage treatment plants (STPs).

The application transfer efficiency of electrodeposition coating is near unity and a typical transfer rate is approximately 97%. The 3% losses include 0.5% lost in water via the ultrafiltrate and 2.5% lost as sludge during the cleaning and rinsing of the electrodip tank. A release of up to 2,500 kg/year (500,000 kg × 0.5%) of the notified polymer is expected to internal WWTPs. Internal WWTPs are expected to remove > 90% of the notified polymer, based on its cationic characteristics and high molecular weight. Therefore, release of the notified polymer to STPs is up to 250 kg/annum (2,500 kg/year × 10%).

RELEASE OF CHEMICAL FROM DISPOSAL
The notified polymer will coat automobile components and will become irreversibly cross-linked to form part of an inert coating matrix during the heat curing process. The cross-linked notified polymer is expected to share the fate of the coated automobile parts, and at the end of the car's useful life, the coated metal articles will be sent to metal reclamation facilities or be disposed of to landfill. Residual notified polymer in empty import containers is expected to be collected by licensed contractors for disposal to landfill.

7.1.2. Environmental Fate
Most of the notified polymer will be cured into an inert, cross-linked matrix as part of the e-coating process. The notified polymer will share the fate of the coated automotive parts, which will involve eventual disposal to landfill or thermal decomposition during metal reclamation. In its cross-linked form, the notified polymer is not expected to be bioavailable or mobile in the environment.

Most of the residues of the notified polymer in waste streams generated from the e-coat process are expected to be captured by on-site WWTPs. However, a small amount of the notified polymer may not be captured by these systems and could be released to the sewer. In sewage treatment plants, most of the notified polymer is expected to be removed in the sludge and sediment based on its potential cationic characteristics and high molecular weight. Sludge from treatment plants may be collected for disposal to landfill or used in soil remediation. The notified polymer is expected to be readily biodegradable (86% over 28 days; OECD 301B) based on studies conducted on an analogue polymer. The notified polymer has potential to partition to organic phases (3.66 g/L solubility in n-octanol). However, it is not expected to bioaccumulate or leach due to its high molecular weight and charge density. In landfill or in remediated soil, it will undergo biotic or abiotic degradation processes. The notified polymer is expected to generate water, oxides of carbon and nitrogen during degradation in landfill or by thermal decomposition.

7.1.3. Predicted Environmental Concentration (PEC)
Based on typical release data for electrodeposition coating at automotive plant, up to 0.96 kg/day (250 kg/annum ÷ 260 working days) of the notified polymer is estimated to be released to sewage treatment plants (STPs). Assuming an average flow of 85 ML/day for a typical individual local STPs and > 90% solids removal during sewage treatment and single site release for the worst case scenario, the PEC can be calculated as 1.13 µg/L (= 0.96 kg/day × 10% ÷ 85 ML/day) for release to a river and 0.11 µg/L (= 1.13 µg/L × 0.1) for release to the ocean.

7.2. Environmental Effects Assessment
The results from ecotoxicological investigations conducted on an analogue polymer are summarised in the table below. For both the fish and Daphnid tests, nominal concentrations of 0.1, 1.8, 3.2, 5.6 and 10 mg/L were used along with a control. The tests were conducted on an aqueous solution containing the analogue polymer (30%) and results are corrected for the active component. The analogue polymer is structurally identical to the notified polymer except for the counterion. Therefore, the tested polymer is considered to be an acceptable analogue for the notified polymer.

Studies on the effects to algae from the notified polymer, or a suitable analogue, were not provided. The algal endpoint for the notified polymer was calculated with a Structure Activity Relationship (SAR) equation based on the cation charge density of the polymer (Boethling and Nabholz, 1997). The predicted endpoint, which has been modified by a mitigation factor to account for the anticipated binding of the polymer with organic carbon in surface waters, is detailed in the table below.

Endpoint	*Result*	*Test method*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) = 1.3 mg/L*	OECD 203	Toxic to fish
Daphnia Toxicity	EC50 (48 h) = 4.0 mg/L*	OECD 202	Toxic to aquatic invertebrates
Algal Toxicity	EC50 (96 h) = 6.3 mg/L	Estimated by SAR	Toxic to algae

* Analogue data

The notified polymer is potentially toxic to algae in surface waters with typical levels of total organic carbon. The SAR estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the polymer. However, this method is not considered sufficient to formally classify the notified polymer for acute and long term hazards.

However, under the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS, United Nations, 2009) the analogue, and by inference, the notified polymer is considered toxic to fish and aquatic invertebrates. Based on this toxicity, the notified polymer is classified as 'Acute Category 2; Toxic to aquatic life'. The notified polymer is expected to be readily biodegradable and, as it is not expected to have significant potential to bioaccumulate, it is not classified for long-term hazard under GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated using the endpoint for the most sensitive trophic level [fish LC50 (96 h) = 1.3 mg/L] and an assessment factor of 500, as although the endpoints for three trophic levels are available, they are derived from the results for an analogue polymer and a SAR estimate based on groupings of broadly related polymers.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish).	1.3	mg/L
Assessment Factor	500	
PNEC:	2.6	µg/L

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) has been calculated below:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	1.13	2.6	0.434
Q - Ocean:	0.11	2.6	0.043

As the risk quotient is less than 1, the notified polymer is not expected to pose a risk to the environment when it is introduced at the proposed maximum annual importation volume and used as proposed. Therefore, based on the PEC/PNEC ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Similar polymer to the notified polymer (30% aqueous solution)

METHOD: OECD TG 401 Acute Oral Toxicity – Limit Test.
- Species/Strain: Rat/Sprague-Dawley Cri CD BR
- Vehicle: None, the test substance was directly administrated by gavage.
- Remarks - Method: No significant protocol deviations. The dosage was adjusted to account for the concentration of the polymer in solution. The appendices to the study with individual animal data were not provided.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5M/5F	2,000 (active ingredient)	0/10

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: None noted during the study
- Effects in Organs: None noted during the study
- Remarks - Results: All animals showed expected gain in bodyweight during the study.

CONCLUSION: The test substance is of low toxicity via the oral route.

TEST FACILITY: Safepharm (1997)

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