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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Amine Adduct in Colours and Chemicals 466-791

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 the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full 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:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Wattyl Australia Pty Ltd (ABN 40 000 035 914)
2-44 Graingers Road
WEST FOOTSCRAY VIC 3012

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical name, Molecular formula, Structural formula, Molecular weight, Spectral data, Methods of detection and determination, Purity, Impurities/residual monomers, Import volume, Confidential details of use, Polymer constituents.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting point, Boiling point, Density, Vapour pressure, Hydrolysis as a function of pH, Partition coefficient, Adsorption/desorption, Dissociation constant, Particle size, Flash point, Flammability limits, Autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Amine Adduct in Colours and Chemicals 466-791

OTHER NAME(S)
Amine adduct

MOLECULAR WEIGHT
Mn > 1000 Da

ANALYTICAL DATA
Reference GPC and MALDI-TOF spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Viscous yellow to amber liquid (for 60% notified polymer in solvent solution)

Property	Value	Data Source/Justification
Melting Point	Not determined	Introduced as a solvent solution.
Boiling Point	Not determined	Introduced as a solvent solution.
Density	< 1000 kg/m^3	MSDS. For 60% notified polymer in solvent solution.
Vapour Pressure	Not determined	Expected to be low based on high molecular weight of notified polymer.
Water Solubility	< 0.5 mg/L at 20°C	Estimated based on the structure. The very low solubility was confirmed by visual inspection of 0.1 g samples that were stirred in water (1, 2, 10, 100 and 200 mL), allowed to settle, and observed periodically for 10 weeks.
Hydrolysis as a Function of pH	Stable	Estimated based on the structure.
Partition Coefficient (n-octanol/water)	Not determined	Not relevant for high molecular weight polymer of this type.
Adsorption/Desorption	Not determined	Expected to be immobile in soil, based on the structure.
Dissociation Constant	Not determined	Amine groups are expected to be ionised in the environmental pH range of 4–9.
Particle Size	Not determined	Introduced as a solvent solution.
Flash Point	27°C	MSDS. For 60% notified polymer in solvent solution.
Flammability	Not determined	Introduced as a solvent solution
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosophores.

DISCUSSION OF PROPERTIES
The notified polymer is insoluble in water and is expected to have a low vapour pressure.

The manufactured solvent solution containing the notified polymer (at ~60%) is highly flammable.

Reactivity
The notified chemical is expected to be stable under normal storage and handling conditions.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be manufactured in Australia as a resin solution containing ~60% of the notified polymer.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	3-10	3-10	3-10	3-10	3-10

PORT OF ENTRY
Not applicable, as the notified polymer will be manufactured in Australia.

IDENTITY OF MANUFACTURER
Wattyl Australia

TRANSPORTATION AND PACKAGING
The notified polymer will be distributed by road or rail from the notifier's manufacturing site in Victoria to customer sites as a resin solution (containing ~60% notified polymer) packaged in 200 L drums and 5 L and 20 L steel pails.

USE
Hardener in two-part epoxy coating system for metal substrates such as tanks (including drinking water tanks), heavy machinery and bolts.

OPERATION DESCRIPTION
Polymer manufacture
The notified polymer will be manufactured as a solvent based solution. The monomers and solvents will be pumped via fixed lines into an enclosed tank where polymerisation occurs. The polymer solution containing ~60% of the notified polymer will be sampled for quality control testing before being pumped directly into 200 L drums for storage. Some of the solution will be transferred into 5 L and 20 L steel pails prior to transport to end-use sites.

End-use
At the end-use sites, the polymer solution containing ~60% of the notified polymer will be mixed with another coating component to form the finished coating product (containing < 20% notified polymer) and applied to metal substrates in industrial settings by brush, roller and airless sprayers.

Maintenance workers at the end-use sites will repair and clean the application equipment.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Manufacture			
Reactor operators	25	8	80-100
Maintenance workers	2	1-2	80-100
Laboratory workers	5	8	80-100
Warehouse workers	4	2-4	100-130
Transport workers	10	1-2	40-50
End-use			
Coating applicators	100	5	20
Coating application maintenance workers	2	1-2	20

EXPOSURE DETAILS
Manufacture, repacking and storage
Reactor operators, laboratory personnel, warehouse staff and maintenance workers in the manufacturing plant may be exposed to the notified polymer at up to 60% in solution as manufactured. Dermal and/ocular exposure may occur during transfer, cleaning and drum or pail-filling operations. Inhalation exposure is not likely given the notified polymer has a low vapour pressure and exposure to aerosols is not expected during the manufacturing process as the polymerisation reaction will be conducted in enclosed vessels with local exhaust ventilation.

Transport

Exposure to the notified polymer (at ~60%) during transport is not expected, except in the unlikely event of an accident where the drums or pails are breached.

End-use
Dermal and ocular exposure to the notified polymer (at up to 60%) may occur during decanting and when mixing to give the final finished coating product containing the notified polymer at < 20%.

Dermal and ocular exposure of workers to the notified polymer (at < 20%) may occur during application of the finished coating to metal substrates by brush, roller and spray, and when cleaning up application equipment. Inhalation exposure to the notified polymer (at < 20%) is also likely during spray application given only natural ventilation is available at the end-use sites.

In all operations, workers are expected to wear as a minimum gloves, goggles and coveralls to minimise potential for exposure. Organic vapour respirators will be available for use and will be expected to be worn by application workers during spray application.

6.1.2. Public exposure
The public may become exposed to substrates coated with the notified polymer via the dermal route. Also exposure by the oral route may occur to drinking water from water tanks lined with coatings containing the notified polymer. However, once the coating is dried and cured, the notified polymer will not be bioavailable and therefore is not expected to be present in the drinking water.

6.2. Human health effects assessment

No toxicity data were submitted. In the absence of toxicological data on the notified polymer, the known hazards of amine hardeners have been considered (DermNet NZ, 2009; HSE, 2003). Furthermore, the toxicity profile of the amine monomer used to synthesise the notified polymer has been used as an analogue for the low molecular weight species.

Toxicokinetics
The notified polymer is not expected to be significantly absorbed across biological membranes, based on the high number average molecular weight (> 1000 Da) and low water solubility. However, some absorption may occur as the notified polymer contains a significant proportion of low molecular weight species.

Irritation and Sensitisation
Amine hardeners are in general known to be irritating or corrosive, potentially affecting the eyes, skin and respiratory tract. They are also considered to be potent sensitisers (DermNet, 2009). Epoxy amine adducts such as the notified polymer are expected to be less irritating and sensitising than lower molecular weight amines (HSE, 2003). The notifier has classified the notified polymer as a skin and eye irritant and identified it as a likely sensitiser.

Acute and repeat dose toxicity
Acute toxicity may occur as the notified polymer contains a significant proportion of low molecular weight species. The effects observed are likely to be similar to, but to a lesser extent, to that observed for low molecular weight amines such as the monomer used to prepare the notified polymer. The amine monomer is considered harmful if swallowed (Oral LD50 rats 1090 mg/kg bw/day (males)) and based on a 28-day repeated dose toxicity study in rats has a NOAEL of 150 mg/kg bw/day (SIDS, 2001). The toxicity observed after exposure via oral and inhalation routes was tissue damage in the digestive and respiratory organs, consistent with its corrosiveness at the site of first contact.

Mutagenicity
The notified polymer does not contain any structural alerts for mutagenicity. Furthermore, the amine monomer was not mutagenic in bacteria. It induced neither chromosomal aberrations in mammalian cells *in vitro* nor micronuclei in mouse marrow *in vivo*. The notified polymer is therefore not expected to be a mutagen.

Health hazard classification
Based on the available data the notified polymer can not be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). However, based on the available data on substances with similar functional groups the notified polymer has been classified by the notifier, and should be considered as a skin and eye irritant and potential skin sensitiser with the following risk phrases:

R36/37/38: Irritating to eyes, respiratory system and skin
R43: May cause sensitisation by skin contact
Cutoffs:
Conc ≥ 20%: Xi; R36/37/38, R43
≥ 1%Conc < 20%: Xi; R43

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Due to the presence of a significant proportion of low molecular weight species, the notified polymer is likely to be irritating to the eye and skin, and gastrointestinal tract if swallowed, and may also act as a skin sensitiser.

Manufacture
The main route of exposure to the notified polymer for workers during manufacture and reformulation is expected to be dermal. The risk to workers is considered to be low due to the limited exposure expected. However, as the risk of sensitisation cannot be ruled out workers should wear coveralls and impervious gloves to prevent exposure as a precaution.

End-use
Dermal, ocular and inhalation exposure is expected to be the primary route of exposure during application of the coatings containing the notifier polymer by brush, roller and spray. Given the lower concentration of the notified polymer (< 20%) in the coatings the risk of irritation will be reduced. However, there is still a risk of sensitisation. Workers most at risk of sensitisation from exposure to the notified polymer will be those applying the coatings by spray. To minimise exposure application workers should wear appropriate PPE including coveralls, impervious gloves, eye protection and organic vapour respirators, particularly during spray application, which should be conducted in accordance with NOHSC National Guidance Material for Spray Painting (NOHSC, 1999).

After application the paint containing the notified polymer will be cured into an inert matrix and the notified polymer will not be bioavailable and hence the risk from exposure to coated products is not considered to be unacceptable.

6.3.2. Public health
The public will only be exposed to the notified polymer after the coating has been applied and cured. Once dried and cured, the notified polymer will not be bioavailable and hence the risk to the public is not considered unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The polymer solution is manufactured and formulated in closed reactors and drummed off for further processing into coating products. Environmental release of the notified polymer is unlikely during manufacture and storage on site. Should a spill occur it will be contained to the plant by existing bunding. The notifier expects that at most 0.5% of the notified polymer (< 50kg at the maximum proposed rate of manufacture) will be lost due to spills that occur during formulation via mixing vessels, holding vessels, filling pots and lines and empty drums. All equipment will be washed with recycled solvent resulting in up to 0.5% (< 50 kg per year) waste of the notified polymer. Wastes will be removed from the site by a licensed waste contractor.

RELEASE OF CHEMICAL FROM USE
Residues in coating containers are expected to account for less than 1% of the import volume of the notified polymer. At the maximum proposed volume of manufacture this would equate to 100 kg of the notified polymer which will be disposed of through drum recyclers or to landfill as container residues.

As a worst case, assuming 100% of the coating is applied through spray application, the maximum total amount of the notified polymer that may need disposal following use of the coatings is 33% (1%$_{container}$ + 30%$_{over\ spray}$ + 2%$_{cleaning}$) of the imported quantity. Thus, at the maximum proposed volume of 10 tonnes per annum, 3300 kg is the maximum that will be disposed of following application.

RELEASE OF CHEMICAL FROM DISPOSAL
The notified polymer is expected to be disposed of to landfill, although some minor waste streams such as equipment washings and container residues may be thermally decomposed to water and oxides of carbon and nitrogen.

7.1.2 Environmental fate

The notified polymer is not expected to be released to the environment. Following use as an ingredient of two part epoxy coating systems for metal substrates, it will be irreversibly cross-linked into the cured coating, which will be a hard, inert film. The ultimate fate of the film depends on the type of metal substrate to which it is applied. Most substrates will be disposed to landfill at the end of their useful life, where the film can be expected to remain immobile and slowly degrade. If coated articles are recycled to reclaim metals, the film will be thermally decomposed to water and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

The notified polymer will not be released to water when it is handled and used as proposed.

7.2. Environmental effects assessment

No ecotoxicity data were submitted

7.2.1 Predicted No-Effect Concentration

The PNEC cannot be calculated as there are no aquatic toxicity data to base it on.

7.3. Environmental risk assessment

The notified polymer has very low water solubility and will not be released to water when it is handled and used as proposed. Following use, it will be irreversibly cross-linked into a hard, inert film. Therefore, the notified polymer is not expected to present a risk to the environment, based on the reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified polymer can not be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). However, based on the available data on substances with similar functional groups the notified polymer has been classified by the notifier, and should be considered as a skin and eye irritant and potential skin sensitiser with the following risk phrases:

R36/37/38: Irritating to eyes, respiratory system and skin
R43: May cause sensitisation by skin contact
Cutoffs:
Conc ≥ 20%: Xi; R36/37/38, R43
≥ 1%Conc < 20%: Xi; R43

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

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Based on the available data on substances with similar functional groups, introducers should apply the following health hazard classification for the notified polymer:

  – R36/37/38: Irritating to eyes, respiratory system and skin
  R43: May cause sensitisation by skin contact
  Cutoffs :
  Conc ≥ 20%: Xi; R36/37/38, R43
  ≥ 1%Conc < 20%: Xi; R43

Health Surveillance

- As the notified polymer is a potential sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

Material Safety Data Sheet

- The MSDS provided by the notifier should be amended as follows:
  – Full disclosure of chemical name of notified polymer due to being considered as a Type 1 ingredient (R43).

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer during manufacture and end-use:
  – Local exhaust ventilation where possible

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  – Avoid skin and eye contact
  – Avoid breathing spray
  – Use of spray paints containing the notified polymer should be in accordance with the NOHSC National Guidance Material for Spray Painting (NOHSC, 1999).

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  – Coveralls
  – Impervious gloves
  – Eye protection

- Organic vapour respirator

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 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 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 hardener for epoxy coating systems, or is likely to change significantly;
- the amount of chemical being introduced has increased from ten tonnes per annum, or is likely to increase, significantly;
- the method of manufacture of the chemical in Australia has changed, or is likely to change, in a way that may result in an increased risk of an adverse effect of the chemical on occupational health and safety, public health, or the environment;
- 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 a 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.

BIBLIOGRAPHY

DermNet NZ (2009) Allergy to epoxy resin, http://dermnetnz.org/dermatitis/epoxy-allergy.html. New Zealand Dermatological Society Incorporated. Updated 15 Jun 2009. Accessed 1 July 2009.

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