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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polyisocyanate in Bayhydur 401-70

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 Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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:

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Bayer MaterialScience Pty Ltd (ABN 18 086 237 765)
17-19 Wangara Road
Cheltenham VIC 3129

PPG Industries Australia Pty Ltd (ABN 82 055 500 939)
McNaughton Road
Clayton VIC 3169

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, other names, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities, use details, and import volume.

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, water solubility, hydrolysis, partition coefficient, adsorption/desorption, flash point, flammability limits.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
CEC/764, CER/37

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polyisocyanate in Bayhydur 401-70

MOLECULAR WEIGHT
Mn >1000 Da

ANALYTICAL DATA
Reference IR, GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99%

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

ADDITIVES/ADJUVANTS None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The notified polymer is in a liquid form. All of the residual monomer content may be released.

DEGRADATION PRODUCTS
On contact with water/moisture the isocyanate group will hydrolyse to an amine which will undergo crosslinking with other isocyanate groups within the polymer.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Liquid

Property	Value	Data Source/Justification
Boiling Point*	138°C at 101.3 kPa	MSDS
Density*	1070 kg/m^3 at 20°C	MSDS
Vapour Pressure*	0.8 kPa at 20°C	MSDS
Water Solubility	Not determined	Not tested due to the presence of end-groups that readily react with water to form carbon dioxide and insoluble polymeric masses.
Hydrolysis as a Function of pH	Not determined	Not tested due to the presence of end-groups that readily react with water to form carbon dioxide and insoluble polymeric masses. The notified polymer contains groups that are expected to hydrolyse only very slowly in the environmental pH range (4–9) at ambient temperature.
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to react with water and octanol to form carbon dioxide and insoluble polymeric masses.
Adsorption/Desorption	Not determined	Not tested due to the presence of end-groups that readily react with water to form carbon dioxide and insoluble polymeric masses.
Dissociation Constant	Not determined	The notified polymer has no dissociable functions.
Flash Point*	~ 40°C	MSDS
Flammability	Not determined	Not expected to be flammable
Autoignition Temperature*	~ 400°C	MSDS
Explosive Properties	Not expected to be explosive	Estimated based on structure

*Refers to Bayhydur 401-70, containing the notified polymer at 20-30% concentration.

DISCUSSION OF PROPERTIES

Reactivity

On contact with water/moisture the isocyanate group will hydrolyse to an amine which will undergo crosslinking with other isocyanate groups within the polymer.

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported either as an ingredient in Bayhydur 401-70 (20-30% concentration) or as part of a formulated hardener/activator component of a coating system (5-20% concentration).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-100	10-100	10-100	10-100	10-100

PORT OF ENTRY

Melbourne and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Bayer MaterialScience Pty Ltd and PPG Industries Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 205L metal drums (Bayhydur 401-70) or 0.5L steel cans (formulated hardeners). It will be transported from the dock to the notifier's warehouse facility by road and then distributed to customer sites also by road.

USE
The notified polymer will be used as a component of hardener products for water based coatings, mainly for aftermarket automotive refinishing at concentrations of 5-20%.

OPERATION DESCRIPTION
The notified polymer may be imported in a finished product (5-20% concentration) or in a more concentrated form (20-30% concentration) for local reformulation into coating/paint products.

Reformulation
The notified polymer (20-30% concentration) will be transferred from import containers by metered dosing and metered pumps to a mixing vessel. It will then be mixed with other ingredients. Each batch will be quality checked and adjusted as required. The resultant paint (5-20% notified polymer) will be manually filtered prior to dispensing into 0.5 to 20L cans for supply to customers.

End-use
The formulated coating/paint products (5-20% notified polymer) will be applied by spray. The majority of the spray applications will occur in a spray booth, though in smaller automotive refinish repair shops spray applications may occur outside of a spray booth.

Thinning may be required, which will involve manual transfer of the coating (5-20% notified polymer) to a container and the addition of extra reducer. It will then be transferred to a reservoir for spray equipment application that will be attached to the spray gun that feeds the gun through aspiration or gravity. It will then be taken to the spray booth and applied to the vehicle.

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)*
Transport and storage	2-4	1-2	20
Reformulation	2-4	4-8	20
QC staff	1-2	1	20
Maintenance	1-2	1-2	20
Spray painting	100-1000	8	300

EXPOSURE DETAILS
Reformulation
Workers may be exposed to notified polymer (concentrations up to 30%) via dermal and ocular exposure due to spills and leaks, during connecting of filling lines, charging of the mixer, blending and quality control operations. Such exposure is expected to be minimised by the wearing of personal protective equipment (PPE) such as coveralls, goggles and impervious gloves. Inhalation exposure of workers to aerosols of the notified polymer may occur during blending. However, such exposure is likely to be low due to the local exhaust ventilation system in place, the enclosure of the mixing vessel during high speed stirring, and the use of a respirator when ventilation is deemed to be inadequate. Dermal exposure may be possible due to drips and spills when connecting filling lines. The paint will be filled into drums under local exhaust ventilation and workers will wear overalls, goggles and impervious gloves to control exposure.

End use
Spray painters may come into contact with the notified polymer at concentrations of up to 20% through dermal and ocular routes from direct contact with drips, spills and splashes during transfer of the paint to the spraying equipment, paint application, and equipment cleaning and maintenance. Such exposure is expected to be minimised by the use of PPE that will include skin and eye protection.

Workers may also be exposed to the notified polymer (concentrations of up to 20%) by inhalation of paint aerosols containing the notified polymer during spray application. Such exposure is expected to be minimised by the majority of spray paint applications occurring in ventilated spray booths with respiratory protection used. When spray booths are not used the level of exposure is expected to be greater, however, it will be lowered by ensuring that spray application occurs in well ventilated areas and that appropriate PPE will be used, particularly respiratory protection.

After application and once dried, the paint containing the notified polymer will be cured into an inert matrix and the polymer is expected to be unavailable for exposure.

6.1.2. Public Exposure
The notified polymer will not be available to the public and as such, exposure is expected to be negligible. The public may come into contact with articles that have been coated with the notified polymer; however, it will be cured into an inert matrix and is not expected to be available for exposure.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer.

The notified polymer is not expected to be absorbed across biological membranes to a significant extent, based on its high molecular weight (Mn > 1000 Da).

The notified polymer contains isocyanate functional groups that are of concern for irritation, dermal and respiratory sensitisation and pulmonary toxicity (Barratt 1994, USEPA 2010, Kirk-Othmer 1995).

The USEPA specifies that structures with isocyanate equivalent weights of ≥5,000 are presumed not to pose a hazard under any conditions. In addition, concerns are generally confined to species with molecular weights <1,000. The isocyanate functional group equivalent weight of the notified polymer is <5,000, however, its molecular weight is >1,000. A relatively low proportion of low molecular weight species are present in the notified polymer. However, at such levels health concerns of the notified polymer associated with the isocyanate functionality cannot be ruled out.

The main hazards posed by isocyanates include respiratory sensitisation in the form of asthma, as well as decreased respiratory function with the possibility of interstitial fibrosis and pulmonary oedema (Tillman, 2007). Isocyanate exposure is the most common cause of occupational asthma around the world (Mapp *et al*., 1988; Bernstein, 1996) and no specific treatment is available for individuals who are sensitised. Individuals with a history of respiratory conditions such as asthma and hay fever may be more likely to develop isocyanate sensitivity (NOHSC, 1990). Polymeric isocyanates are less volatile and contain less free isocyanate, and are therefore expected to be less of an inhalation hazard. However, the UK Employment Medical Advisory Service believes polymeric isocyanate aerosols are capable of causing respiratory sensitisation similar to monomer vapours, and reports have shown that inhalation of relatively non-volatile isocyanates in the form of dusts and spray-mists could cause adverse respiratory effects (HSIS, 2008). Isocyanates may also cause respiratory sensitisation by skin contact (US EPA 2010).

Isocyanates may be irritating to the skin and eyes and splashes in the eyes may lead to severe chemical conjunctivitis (NOHSC, 1990). In addition, isocyanates may cause skin sensitisation from repeated or prolonged exposure (Kirk-Othmer, 1995). The potential for these effects is likely to be reduced due to the high molecular weight of the notified polymer.

According to the Approved Criteria (NOHSC 2004), substances containing isocyanate functional groups should be classified as hazardous if there is no evidence to indicate that the substance does not cause respiratory hypersensitivity. Thus, the following risk phrase should be applied to the notified polymer:
R42 May cause sensitisation by inhalation.

Health hazard classification
Based on the presence of the isocyanate functional group in the notified polymer, the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:.

Xn; R42 May cause sensitisation by inhalation.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Toxicological data was not supplied for the notified polymer. On the basis of the presence of isocyanate functional groups, the notified polymer may cause irritation, dermal and respiratory sensitisation and pulmonary toxicity. Such effects cannot be ruled out, though they are expected to be reduced by the relatively low proportion of low molecular weight species present in the notified polymer. Workers exposed to isocyanates may have a concentration-dependent risk of developing respiratory diseases such as bronchial asthma (Baur *et al*., 1994) and often the only treatment for sensitised individuals is to completely remove the worker from the workplace to avoid exposure (Bernstein, 1996). Therefore, measures should be in place to avoid workers developing respiratory sensitisation.

Inhalation exposure of workers to the notified polymer (up to 20% concentration) may occur, particularly inhalation of aerosols of the notified polymer during end use spray application. The majority of spray application is expected to take place in ventilated spray booths with respiratory protection that should lower the potential for inhalation exposure to occur and thus also the potential for adverse respiratory effects. When spray operations do not occur in spray booths there is a greater risk of adverse respiratory effects. This risk should be lowered by ensuring that the application area is well ventilated and that appropriate respiratory protection is worn.

Employers should ensure that airborne levels of isocyanates remain below the exposure standard set by Safe Work Australia in all areas where spray operations occur [NOHSC: 1003(1995)]. Where respiratory protection is deemed to be appropriate for reducing isocyanate exposure, it should consist of an appropriately fitted and maintained air-line respirator or self-contained breathing apparatus complying with the appropriate Australian Standard.

Dermal exposure is one of the main potential routes of worker exposure to the notified polymer (up to 30% concentration) during reformulation and end use. Irritation and sensitisation may occur as a result of dermal exposure. Dermal exposure is expected to be minimised by the automated processes in place for many of the transfer, blending and quality control operations, the local exhaust ventilation in place, the use of spray booths and the wearing of personal protective equipment by workers, including gloves, goggles, and coveralls.

It is noted that the measures in place to minimise risks involved in handling the other hazardous substances present in the product containing the notified polymer are expected to correspondingly reduce the risk associated with handling of the notified polymer.

In summary, the risk to workers associated with exposure to the notified polymer is not considered unreasonable provided that the stated engineering controls (particularly spray booths), safe work practices and appropriately fitted and maintained PPE (particularly respiratory protection, but also gloves, goggles and coveralls) are used.

6.3.2. Public Health
No public exposure to the notified polymer is expected from the cured coated material. As such, the risk to the public from the use of the notified polymer is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Release of the notified polymer to the environment during importation, storage, and transport is unlikely. The most likely source of a release to the environment during these activities will be a transport accident. Up to 1% of the import volume is expected to be lost during spillage. If a spill occurs during storage or transportation, products containing the notified polymer are expected to be absorbed into inert materials (e.g. sand, soil, vermiculite, etc.) and collected into suitable containers for disposal to landfill.

RELEASE OF CHEMICAL FROM USE

Reformulation wastes, container residues and fully cured solid wastes, which contain the notified polymer, are expected to be collected and sent to landfill. The main release as overspray (35%) during use will typically entail landfill disposal, after interception by spray booth filters. Equipment used to apply the coating formulations may be rinsed with solvent. It is expected that a small amount (≤1%) of the notified polymer from cleaning of equipment will be collected, treated and disposed of to landfill in accordance with local, State and Federal regulations. Once cured, the coatings containing the notified polymer will form an inert polymer matrix, and the incorporated notified polymer will not be bioavailable.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer in coatings is expected to share the fate of the automobiles to which it has been applied. It will therefore either be thermally decomposed during metal reclamation processes or disposed of to landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified polymer is expected to be cured into an inert matrix as part of its normal use pattern as a component in automotive coatings. The notified polymer is irreversibly bound into the matrix and, in this form, is not expected to be bioavailable or biodegradable. The notified polymer in solid waste disposed of to landfill, is not expected to be mobile and will slowly degrade *in situ*, primarily by abiotic processes. The notified polymer will eventually degrade in landfill or by thermal decomposition during metal reclamation processes, to form water and oxides of carbon and nitrogen.

Significant amounts of the notified polymer are not expected to be released to the aquatic environment. However, if residues are washed to sewer from cleaning of formulation and application equipment, the notified polymer is expected to partition to sludge during sewage treatment. Bioaccumulation of the notified polymer is unlikely due to its high molecular weight and its limited release to surface waters.

7.1.3. Predicted Environmental Concentration (PEC)

Significant concentrations of the notified polymer are not expected in the aquatic environment based on the limited possibility for release and the low water solubility of the notified polymer. The PEC for the notified polymer has therefore not been calculated.

7.2. Environmental Effects Assessment

No ecotoxicity data of the notified polymer were submitted. The notified polymer will form an inert mass via crosslinking of isocyanate groups on exposure to water. Therefore, the notified polymer is not expected to be bio-available in the unlikely event that it is released to aquatic ecosystems.

7.2.1. Predicted No-Effect Concentration

As no suitable ecotoxicity data are available for the notified polymer, no PNEC can be calculated.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified polymer has not been calculated as release to the aquatic environment in ecotoxicologically significant quantities is not expected based on its assessed use pattern as a component in automotive coatings. The majority of the notified polymer will be disposed of to landfill as cured coating. In its cured state the notified polymer will be irreversibly bound into the inert coating matrix and is unlikely to leach or be bioavailable. Due to its limited environmental exposure, the notified polymer is not considered to pose an unreasonable risk.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the information provided, the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] with the following risk phrase:

Xn; R42 May cause sensitisation by inhalation

and

The classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Respiratory sensitisation	1	May cause allergy or asthma symptoms or breathing difficulties if inhaled

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

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Safe Work Australia, should consider the following health hazard classification for the notified polymer:
  - Conc. ≥ 1%: R42 may cause sensitisation by inhalation

Health Surveillance

- As the notified polymer contains isocyanate functional groups, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a history of isocyanate sensitivity, asthma or other pulmonary condition and who may be adversely affected by isocyanate exposure.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified polymer during reformulation and use of products containing the notified polymer:
  - Ventilation systems including local exhaust ventilation when inhalation exposure could occur, where possible.
  - Automated processes, where possible.
  - Ventilated spray booths during spray application, where possible.
  - Spray application to occur in well-ventilated areas when spray booths cannot be used.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer during reformulation and use of products containing the notified polymer:
  - Keep containers securely sealed and check regularly for spills and leaks.
  - Avoid inhalation of vapours, mists and aerosols.
  - Avoid contact with skin and eyes.
  - Wash hands after handling the notified polymer, or containers and equipment containing it.

- Spray application should be carried out in accordance with the Safe Work Australia 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 during reformulation and use of products containing the notified polymer:
  - Isocyanate-resistant gloves
  - Coveralls
  - Safety glasses
  - Appropriate respiratory protection for any process where inhalation exposure may occur.

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

- Atmospheric monitoring should be conducted to measure workplace concentrations of isocyanates during reformulation and use of products containing the notified polymer. Employers should ensure that the exposure standard for isocyanates [NOHSC: 1003(1995)] is not exceeded for all areas where the notified polymer will be handled.

- 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 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 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

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of hardener products, or is likely to change significantly;
- the amount of polymer being introduced has increased from 100 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 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.

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