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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Isocyanate in Macroplast CR4200

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)
Henkel Australia Pty Ltd (ABN: 82 001 302 996)
135-141 Canterbury Road
Kilsyth, VIC 3137

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, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Macroplast CR4200 (<40% notified polymer)

MOLECULAR WEIGHT
>1,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY <40%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	Benzene, 1,1'-methylenebis[4-isocyanato-
CAS No.	101-68-8 *Weight %* 10-30%
Hazardous Properties	R40(3); Xn; R20-R48/20 Xi; R36/37/38; R42/43 Conc. ≥25%: Xn; R40; R20; R48/20; R36/37/38; R42/43 ≥10% Conc. <25%: Xn; R40; R48/20; R36/37/38; R42/43 ≥5% Conc. <10%: Xn; R40; R36/37/38; R42/43 ≥1% Conc. <5%: Xn; R40; R42/43 ≥0.1% Conc. <1%: Xn; R42
Chemical Name	Benzene, 1-isocyanato-2-[(4-isocyanatophenyl)methyl]-
CAS No.	5873-54-1 *Weight %* 30-60%
Hazardous Properties	R40(3); Xn; R20-R48/20 Xi; R36/37/38; R42/43 Conc. ≥25%: Xn; R40; R20; R48/20; R36/37/38; R42/43 ≥10% Conc. <25%: Xn; R40; R48/20; R36/37/38; R42/43 ≥5% Conc. <10%: Xn; R40; R36/37/38; R42/43

≥1% Conc. <5%: Xn; R40; R42/43
≥0.1% Conc. <1%: Xn; R42

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20ºC AND 101.3 kPa: pale yellow liquid*

Property	Value	Data Source/Justification
Boiling Point	>300 ºC at 101.3 kPa*	MSDS
Density	1222 kg/m^3 at 20 ºC*	MSDS
Vapour Pressure	Not determined	Based on the high molecular weight, vapour pressure is expected to be low.
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
Partition Coefficient (n-octanol/water)	Not determined	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 functional groups
Flash Point	>200 ºC*	MSDS
Autoignition Temperature	Not determined	Not expected to autoignite based on flash point.
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.

*Macroplast CR4200 containing <40% notified polymer

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
The notified polymer contains reactive isocyanate functional groups. It will react in end-use when mixed with the other component of a 2-part resin. Polymerisation may occur at temperatures above 200 ºC.

Dangerous Goods classification
Based on the limited 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 as Macroplast CR4200 (at <40% concentration).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<21	<21	<21	<21	<21

PORT OF ENTRY

Melbourne and Sydney (sea and air).

IDENTITY OF MANUFACTURER/RECIPIENTS
Henkel Australia Pty Ltd.

TRANSPORTATION AND PACKAGING
The notified polymer will be supplied in 240 kg hermetically sealed steel drums. The drums will then be transported within Australia by road.

USE
The imported product containing the notified polymer (at <40% concentration) will be used as one component of a two-part casting resin system. The manufactured parts will have drinking water contact applications.

OPERATION DESCRIPTION
Upon delivery to manufacturing sites, the drums containing the notified polymer (<40%) will be moved from the storage area to the application area and the seal of the drum/pails will be broken. The resin will, in general, be applied using fully automated meter mixing, which will deposit both components of the two-part system at the required ratio into a mould (on occasion, the components may be mixed and dispensed manually). The articles will then be racked and cured in ventilated areas. Curing will take place at 40-60 ºC and will typically take 2-3 days. Finished articles will then be distributed for end-use.

Applicator machines will be cleaned by flushing with solvent.

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	≤5	1	200
Application operations	2	6	100
Cleaning and maintenance	1	0.5	100
Product inspection	1	2	40

EXPOSURE DETAILS
Transport and storage workers may come into contact with the imported product (<40% notified polymer) only in the event of accidental rupture of containers.

In general, the resin application will be an automated process with local exhaust ventilation. Dermal or ocular exposure to the notified polymer may occur during transfer processes, during cleaning and maintenance of equipment and on occasions where manual mixing/dispensing is required. Exposure will be mitigated by the use of exhaust ventilation and personal protective equipment (PPE: chemical goggles, impervious gloves and appropriate industrial clothing). Due to the nature of the processes and the expected low volatility of the notified polymer, inhalation exposure is not anticipated.

Once the resin is cured, the notified polymer is not expected to be bioavailable and further dermal contact should not lead to exposure.

6.1.2. Public Exposure
The notified polymer is intended for industrial use only, therefore the public may be exposed to the imported product (<40% notified polymer) only in the event of a transport accident. The public may be exposed to the manufactured articles. However, once the material is cured, it will be unavailable for exposure.

The manufactured articles will have contact with drinking water. No migration studies for the notified polymer are available. However, the notifier has advised that the notified polymer is not expected to migrate from the articles as it will be cured into the inert matrix of the product.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

Based on the high molecular weight (>1000 Da) of the notified polymer, the potential of the notified polymer to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure is limited. However, the polymer contains a proportion of low molecular weight species (MW <1000 Da) that may be absorbed.

Isocyanates are known to be hazardous to human health. 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). The UK Employment Medical Advisory Service believes polymeric isocyanate aerosols are capable of causing respiratory sensitisation similar to monomer vapours (ASCC). Isocyanates may also cause respiratory sensitisation by skin contact (US EPA, 2010). Other adverse health effects of isocyanates may include skin and eye irritation, and skin sensitisation from repeated or prolonged exposure (Kirk-Othmer, 1995). Although the potential for these effects is likely to be reduced due to the high molecular weight of the notified polymer, these effects cannot be ruled out.

Health hazard classification
Based on the presence of the isocyanate functional group in the notified polymer, it 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
The notified polymer will be handled by workers at <40% concentration. At such concentrations, the notified polymer is classified as a respiratory sensitiser and is a potential eye and skin irritant and skin sensitiser. Dermal and ocular exposure to the notified polymer during operations involving the uncured resin is expected to be limited by the use of PPE. Due to the expected low volatility of the notified polymer and given that exhaust ventilation will be used, inhalation exposure is not anticipated. Therefore, provided control measures are in place to reduce exposure, the risk to the health of workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health
The notified polymer is intended for use in industrial applications by qualified operators. The public may be exposed to products manufactured using the polymer, in-particular products with drinking water applications. A quantitative assessment of consumption of drinking water, as a potential source of exposure if the notified chemical is leached from the articles has not been undertaken. However, the notifier has advised that it is not expected to migrate from the articles as it will be cured into the inert matrix of the product. Therefore, when used in the proposed manner, the risk to public health 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
The notified polymer is imported as a component of a two-part casting resin system and will not be repackaged or reformulated in Australia. Accidental spills during transport are expected to be absorbed onto suitable material (e.g. vermiculite) and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The product containing the notified polymer will be mixed and deposited into moulds using a fully automated meter mixing machine. The articles produced from the moulds will then be racked and cured. The equipment in contact with the notified polymer will be flushed periodically with dichloromethane and any residues of the polymer are expected to be collected and sent to a licensed waste disposal contractor for disposal according to State/Territory regulations. A small amount of notified polymer is anticipated to be released to the environment due to equipment cleaning (< 1%) and container residues (< 1%).

RELEASE OF CHEMICAL FROM DISPOSAL

The fate of the majority of the imported quantity of notified polymer will be tied to the fate of the articles that contain the notified polymer in cured form. The cured notified polymer is therefore expected to be disposed of to landfill at the end of the articles' useful life.

7.1.2. Environmental Fate

No environmental fate data for the notified polymer were provided. Summaries of literature and unpublished studies were provided for analogues with identical reactive functional groups to the notified polymer in reliable internationally peer-reviewed publications.

Analogue 1 is known to rapidly react in water with a half life of up to one minute. Due to this high reactivity, Analogue 1 only exists transiently in water and is essentially unavailable for uptake, bioaccumulation and biodegradation. This has been shown in a literature study, where Analogue 1 was added to an artificial pond up to a concentration of 10 g / L and could not be detected (LOD = 0.006 mg/L) over the course of 112 days of the study. When Analogue 1 is added to water, its end groups readily react with water to form products, which in turn readily react with the parent compound to produce intractable solid polymers. The polymer crust that is formed under environmental conditions (that is, poor dispersion) can slow the rate of hydrolysis of the analogue. A study showed that the degradation rate (half life) of Analogue 1 spilled in a natural aquatic environment (where hydrological conditions correspond to moderate mixing of the spill and temperatures as low as 12ºC) would be approximately 143 hours. An Activated Sludge, Respiration Inhibition test was carried out on a mixture of Analogue 1 and Analogue 2 (polymeric Analogue 1) according to OECD TG 209. No inhibition of activated sludge respiration was observed at 100 mg (Analogue 1) / L of test medium.

Two Inherent Biodegradability tests were performed on analogues of the notified polymer according to OECD TG 302C (Modified MITI (II)). The first study was conducted on a mixture of Analogue 1 and 2 and did not detect any biodegradation with a concentration of 30 mg Analogue 1 / L after 28 days. The second study also did not detect any biodegradation of Analogue 1.

The analogues tested in environmental fate studies most likely formed intractable solid polymers and hence the results pertain to the reaction products with water rather than the analogues themselves. However, the notified polymer is expected to form similar reaction products on contact with water and the results are therefore relevant to the notified polymer. It can be concluded that Analogue 1 and its reaction products with water, and by inference the notified polymer, are not inherently degradable or readily biodegradable. Analogue 1, and by inference the notified polymer, does not inhibit waste water microbial respiration. The notified polymer is expected to be cured into a solid polymer matrix as part of its normal use pattern and is not therefore expected to be bioavailable or biodegradable.

7.1.3. Predicted Environmental Concentration (PEC)

A predicted environmental concentration was not determined because the notified polymer is not expected to persist in water due to its hydrolytic instability. Moreover, very limited aquatic exposure to the notified polymer or its hydrolysis products is expected when the notified polymer is used as proposed.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymer. Summaries of study results were however provided for acceptable analogues with identical reactive functional groups to the notified polymer from reliable internationally peer-reviewed publications. The lowest relevant ecotoxicity endpoints from the submitted studies are outlined below. A discussion of the submitted results follows the table.

The reliability indexes for the tests indicated that they all fell into one of two categories. Either they were not done to test guidelines, or done in accordance with test guidelines but without monitoring of the test substance, or fell short of highest standards of protocol or reporting. The tests are considered reliable for regulatory purposes as monitoring of the test substances would have been impossible due to their hydrolytic instability. Moreover the endpoints are well above expected environmentally relevant concentrations.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (24 hour)*	NOEL = 500 mg/L	Not harmful to fish
Daphnia Toxicity (24 hours)*	EL50 = 129.7 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity (72 hours) OECD TG 201	NOEL = 1640 mg/L	Not harmful to algae
Inhibition of Bacterial Respiration (3 hours) OECD TG 209	IL50 >100 mg/L	Does not inhibit respiration of waste water microorganisms

*Non OECD guidelines

Fish Studies

Concise test details and toxicity endpoints for acute fish studies on Analogue 1 (1 study) and Analogue 2 (5 studies) were submitted by the notifier. The tests had nominal test substance concentrations of 500 – 3,000 mg/L and no lethal effects were observed in any of the studies. The lowest concentration tested was 500 mg/L so this was equated to the NOEL. The notified polymer is therefore considered to be not harmful to fish.

Two long term fish studies were submitted. No direct toxic effects have been observed in studies with nominal concentrations in the range 0.1 – 10,000 mg/L. An indirect impact was observed on fish through decrease of their natural food (cladocerans) in an artificial pond to which was added 10,000 mg/L of Analogue 2. This result is not considered relevant as the loading rate is much greater than the expected environmental release.

Daphnia Studies

Concise test details and toxicity endpoints for acute daphnia studies on Analogue 1 (2 studies) and Analogue 2 (3 studies) were submitted by the notifier. The tests had nominal test substance concentrations of 0.5 – 3,000 mg/L and no lethal effects were observed except in one study. In this study Analogue 2 was dispersed into the medium by high speed shearing rather than the usual stirring method. This was thought to have led to an increased production of a product to which invertebrates are known to be sensitive (EC50 for *Moina macropa* = 2.3 mg/L). The authors considered these data as irrelevant because the dispersing method does not reflect a plausible exposure mechanism in the environment. In the same study the endpoint obtained when the test substance was magnetically stirred was an EC50 >1000 mg/L.

Two long-term studies showed that Analogue 2 had indirect effects on aquatic invertebrates. In the study there was a physical effect noted on benthic organisms. On a local scale an accidental spill would have a dramatic effect on those organisms. However, the authors thought that if the crust was removed from the sediment as a restoration measure, a re-colonisation by animals from the surroundings would rapidly occur.

Algae Studies

Concise test details and toxicity endpoints for algal studies on Analogue 2 (3 studies) were submitted by the notifier. The tests had nominal test substance concentrations of 3 – 10,000 mg/L and no significant effects were observed except the physical hindrance of macrophyte emergence due to the polymeric solid crust formation.

Microorganism Studies

Concise test details and toxicity endpoints for two microorganism studies on Analogue 2 were submitted by the notifier. No toxic effect was observed on microorganisms, but as in all the other tests, the analogue would have reacted with water producing insoluble polymeric masses.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as no significant aquatic exposure is expected based on its reported use pattern.

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 is not expected based on its reported use pattern as a component in a two-part casting resin system that is only used industrially, in a controlled factory environment. All ecotoxicological endpoints for short term studies on analogues to the notified polymer were above 100 mg/L (loading rate), indicating the notified polymer is not harmful to aquatic organisms. This finding was most likely due to the formation of intractable polymeric masses on contact with water, which are expected to be neither bioavailable or bioaccumulative. Effects observed in long term studies were either due to physical effects on organisms or at concentrations that are not environmentally relevant. The majority of the notified polymer will be disposed of to landfill as cured polymer. Once cured, the notified polymer is irreversibly bound into a solid inert matrix, and is unlikely to be

bioavailable or leach in this form. The notified polymer is therefore not expected to pose an unreasonable risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the presence of the isocyanate functional group in the notified polymer, it 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

Due to the lack of toxicological data, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2009) was not carried out.

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 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:
  - Xn; R42 May cause sensitisation by inhalation

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - Conc. ≥1%: Xn; R42

- As the polymer is a Type 1 Ingredient, the applicant should ensure that the labels for products containing the polymer are acceptable to the relevant state authority.

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:
  - Ventilation system including local exhaust ventilation.
  - Automated processes, where possible.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of 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.
- Wash hands after handling the notified polymer, or containers and equipment containing it.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Gloves
  - Overalls
  - Safety glasses
  - Organic vapour respirator (as needed)

  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 volatile resin components during use of the notified polymer. The Safe Work Australia exposure standard for isocyanates is 0.02 mg/m^3 (TWA) and 0.07 mg/m^3 (STEL).

- 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 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;
  - the polymer is imported in a mixture that can be aerosolised;
  - information has become available to the person on the dermal sensitisation potential of the notified polymer.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a component of a resin, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 21 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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