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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer (DWK4200) in DWL 4070.01

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:

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Director
NICNAS

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FULL PUBLIC REPORT

Polymer (DWK4200) in DWL 4070.01

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Dow Chemical (Australia) Ltd (ABN: 72 000 264 979)
541-583 Kororoit Creek Road
Altona VIC 3018

NOTIFICATION CATEGORY
Polymer of Low Concern

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, Import Volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
DWK4200
DWK4200.01 Developmental Polyol
DWL4070.01 (~50% notified polymer)
DWL4070.01 Developmental Polyol (~50% notified polymer)

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >1000 Da

REACTIVE FUNCTIONAL GROUPS
The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Colourless to yellow viscous liquid
Freezing Point	-2 to 6°C
Boiling Point	No boiling was observed below the temperature at which reaction or decomposition started (approx 300°C).
Density	990 kg/m^3
Vapour Pressure	(2.6 ± 2) x 10^{-4} kPa at 20°C (measured using vapour pressure curve, static method). The notified polymer itself is expected to have very low vapour pressure because of its high molecular weight. The measured vapour pressure most likely reflects the presence of low molecular weight impurities such as residual monomers.
Water Solubility	< 1.0 mg/L at 20.3 ± 0.4°C (flask method). Low water solubility is expected from the mainly hydrophobic structure of the notified polymer.
Dissociation Constant	Not applicable. There are no groups that can undergo dissociation in the environmental pH range of 4–9.
Flash Point	No flash-point determined up to 300-310°C (Pensky-Martens Closed Cup Test)
Reactivity	Stable under normal use conditions.
Degradation Products	None known under normal conditions of use. The notified polymer contains some hydrolysable functionalities. However, hydrolysis is unlikely to occur under ambient abiotic conditions in the environmental pH range of 4–9 because of the low solubility of the notified polymer.

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<50	<100	≤100	<250	≤250

Use
The notified polymer will be used as the polyol component in flexible polyurethane foam products such as furniture and bedding applications.

The notified polymer will be pumped into a holding tank and the required volume automatically dosed to the mixing head where it will be mixed with an isocyanate to produce polyurethane foam. The mixture is extruded onto a conveyor where curing takes place. The foam will then be cut into slabs inside the machinery.

Mode of Introduction and Disposal
The notified polymer will be imported as a 50% mixture in 200L steel drums or 1800L isotainers and transported by road to foam production facilities.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation
The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the notified polymer and analogue polymers.

Endpoint	*Result*	*Classified?*	*Effects Observed?*	*Test Guideline*
1. Rat, acute oral (1)	LD50 > 2000 mg/kg bw	no	yes	OECD TG 423
1. Rat, acute oral (2)	LD50 > 2000 mg/kg bw	no	no	Up and Down Procedure
2. Rat, acute dermal (1)	LD50 > 2000 mg/kg bw	no	yes	OECD TG 402

2. Rat, acute dermal (2) (analogue)	LD50 > 2000 mg/kg bw	no	no	Limit test
3. Rabbit, skin irritation	non-irritating	no	yes	OECD TG 404
4. Rabbit, eye irritation (1)	slightly irritating	no	yes	OECD TG 405
4. Rabbit, eye irritation (2) (analogue)	slightly irritating	no	yes	OECD TG 405
5. Skin sensitisation - adjuvant test	no evidence of sensitisation	no	yes	OECD TG 406 (guinea pig maximisation test)
6. Rat, oral repeat dose toxicity - 28 days.	NOAEL 1000 mg/kg bw	no	yes	OECD TG 407
7. Genotoxicity - bacterial reverse mutation	non mutagenic	no	no	OECD TG 471
8. Genotoxicity – in vitro <chromosome aberrations in cultured peripheral human lymphocytes>	non genotoxic	no	no	OECD TG 473

Discussion of Effects Observed

Rat, acute oral (1):
- Hunched posture observed in 3/6 animals on Day 1.

Rat, acute dermal (1):
- One male found dead on Day 1 (total of 10 test animals);
- Lethargy, hunched posture, piloerection, chromodacryorrhoea and/or ptosis observed in most males on Days 1 and 2;
- Hunched posture and/or chromodacryorrhoea observed in 2 females on Day 1.
- Scales were seen in the treated skin area of one female on day 3 and 4.

Rabbit, skin irritation:
- Very slight erythema was observed in 2/3 male animals at the one hour observation.

Rabbit eye irritation (1):
- All 3 animals exhibited slight chemosis and discharge at the one hour observation. All animals also displayed slight/moderate redness, which resolved within 48 hours (mean score of 0.3 for all animals calculated using scores at 24, 48 and 72 hour observation points).

Rabbit eye irritation (2):
- One hour after test substance instillation, all three treated eyes exhibited slight to moderate conjunctivitis. The mean scores were 1.3, 0, and 0.7 for redness, chemosis and discharge, respectively (calculated using scores at 24, 48 and 72 hour observation points). The overall incidence and severity of irritation decreased with time, and was resolved by day 4.

Skin sensitisation - adjuvant test:
- Following first challenge with 100% test item, skin reactions were observed in 2/10 test animals, but not in control animals. Following second challenge, no reactions were observed in the test or control animals.

Rat 28 day repeat oral dose:
- Some statistically significant changes in clinical biochemistry parameters were observed in males treated at the highest dose. As these changes were not dose related and were only mild in nature, they were not considered to be of toxicological significance.
- Some statistically significant changes in liver weights were observed. However, given that the liver weights remained within the range expected for such rats, and the absence of corresponding changes to suggest liver injury or hepatotoxicity, these effects were not considered to be adverse.

The above results suggest the notified polymer to be a slight irritant that may be absorbed transdermally and cause adverse effects. The absorbed species are most likely low molecular weight species or impurities. Such effects may not be of significance in humans, given that rat and rabbit skin is more permeable than human skin. The observed effects were not of sufficient severity for classification.

Occupational Health and Safety Risk Assessment
Dermal and ocular exposure may potentially occur during certain processes involving the notified polymer. However, exposure to significant amounts of the notified polymer is limited and expected to be of relatively short duration due to the automated and enclosed processes used. The notified polymer is not expected to cause significant effects in exposed workers.

Overall, the OHS risk presented by the notified polymer is not considered to be unacceptable, based on the minimal exposure to workers and the low hazard of the polymer.

Public Health Risk Assessment
The notified polymer will not be sold to the public except in the form of finished articles. There is potential for public exposure to articles such as foam in bedding and furniture comprised partly of the notified polymer. In such foams the notified polymer is expected to be in a cured, immobile state and as such exposure is expected to be low. Overall, the risk to the public presented by the notified polymer is expected to be low, based on the minimal exposure and the low intrinsic hazard of the polymer.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation
The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by environmental endpoints observed in testing conducted on the notified polymer.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
Fish Toxicity	LC50 > 100 mg/L	no	OECD TG 203
Daphnia Toxicity	EC50 > 100 mg/L	yes	OECD TG 202
Algal Toxicity	EC50 > 100 mg/L	no	OECD TG 201

All results were indicative of low hazard. The results tabulated above are from testing with water accommodated fractions. Effects observed in daphnids reflect physical fouling by undissolved material rather than chemical toxicity.

Environmental Risk Assessment
The low water solubility of the notified polymer, its relatively high molecular weight and the inert nature of the polyurethane foam indicate that the polymer is not expected to be mobile within landfill sites. The risk to the environment is considered to be acceptably low based on the expected limited release, the low solubility in water of the polymer, its high molecular weight and its rapid biodegradation once dispersed through the environment at low concentrations.

8. CONCLUSIONS AND RECOMMENDATIONS

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

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

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

Recommendations

CONTROL MEASURES
Occupational Health and Safety

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

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

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

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

Environment

Disposal

- The notified polymer should be disposed of by landfill.

Emergency procedures

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

Regulatory Obligations

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

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

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

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the notified polymer has changed from a polyol component in flexible polyurethane foam products, or is likely to change significantly;
  - the amount of notified polymer being introduced has increased from 250 tonnes per annum, or is likely to increase, significantly;
  - if the notified polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

Material Safety Data Sheet
The MSDS of the notified polymer (and products containing the notified polymer) provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.