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24 January 2008

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Genomer 6050

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 in Genomer 6050

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Plastral Pty Ltd
11B Lachlan Street
WATERLOO NSW 2015

Siegwerk Australia Pty Ltd
118 Swann Drive
DERRIMUT VIC 3030

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 Formula, Structural Formula, Molecular Weight, Spectral Data, Purity, Identity of Toxic or Hazardous Impurities, % Weight toxic or hazardous impurities, Polymer Constituents, Identity of additives, % Weight of additives.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting/Boiling Point, Hydrolysis as a function of pH, Adsorption/Desorption, Dissociation Constant, Flammability, Autoiginition temperature, Explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2002)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
GENOMER 6050, GENOMER 6050/TM, GENOMER 6050/GP, GENOMER 6050/ETM, GENOMER 6050/TP

MOLECULAR WEIGHT
>1000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >98%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Clear, yellow-coloured viscous solid to liquid*

Property	Value	Data Source/Justification
Transition Glass Temperature	12°C	Measured
Boiling Point	Not determined	The product containing the notified polymer

		may polymerise at temperatures >170°C.
Density	1240 kg/m^3 at 20°C	Measured
Vapour Pressure	Negligible	Estimated based on high viscosity and high molecular weight of notified polymer.
Water Solubility	0.0385 g/L at 23°C	Measured
n-Octanol Solubility	6.1 g/L at 23°C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities but should not hydrolyse in environmental pH range 4-9 due to low solubility.
Partition Coefficient (n-octanol/water)	log Pow at 20°C = 1.76	Measured
Adsorption/Desorption	Not determined	Based on log Pow may be expected to be moderately mobile in soils.
Dissociation Constant	Not determined	Contains no dissociable groups.
Viscosity*	100000 – 150000 mPa.s	MSDS*
Flash Point*	>100°C	MSDS*
Flammability	Not expected to be highly flammable	Based on its reactivity and low vapour pressure.
Autoignition Temperature	Not determined	The notified polymer decomposes at temperatures >320°C.
Explosive Properties	Not determined	Product containing the notified polymer may polymerise at temperatures >170°C. A DSC chart was provided demonstrating that while the polymerisation reaction is exothermic, it is not explosive.

* Properties marked with an asterisk were determined for the product GENOMER 6050/ETM

DISCUSSION OF PROPERTIES

The notified polymer is hydrophobic and highly viscous. For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity

The notified polymer is expected to be stable under normal conditions of use. Polymerisation of product containing the notified polymer may be initiated by prolonged exposure to temperatures above 75°C, white light or ultraviolet light. Exothermic polymerisation may occur upon contact with radical forming initiators, peroxides, strong alkalis or reactive metals.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported into Australia as a component of finished printing inks; or as a stand-alone component (diluted in acrylic esters) to be sold to ink, coatings or adhesive manufacturers.

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

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

PORT OF ENTRY: Melbourne

IDENTITY OF RECIPIENTS

Siegwerk Australia Pty Ltd
Plastral Pty Ltd

TRANSPORTATION AND PACKAGING

The notified polymer, diluted in acrylic esters, will be imported by sea in 20 kg pails or 220 kg drums.

Finished printing inks containing the notified polymer will be imported by sea packed in 2.5 kg, 20 kg, 200 kg and potentially 1000 kg steel or plastic containers, ready for supply to customers. The notified polymer will be stored at warehouses in Derrimut VIC, Smithfield NSW, Stafford QLD and Camden Park SA.

Transportation of the notified polymer and products containing the notified polymer will be via conventional road transport.

USE
The notified polymer will be used as a component of radically (UV) curable inks, coatings and adhesives.

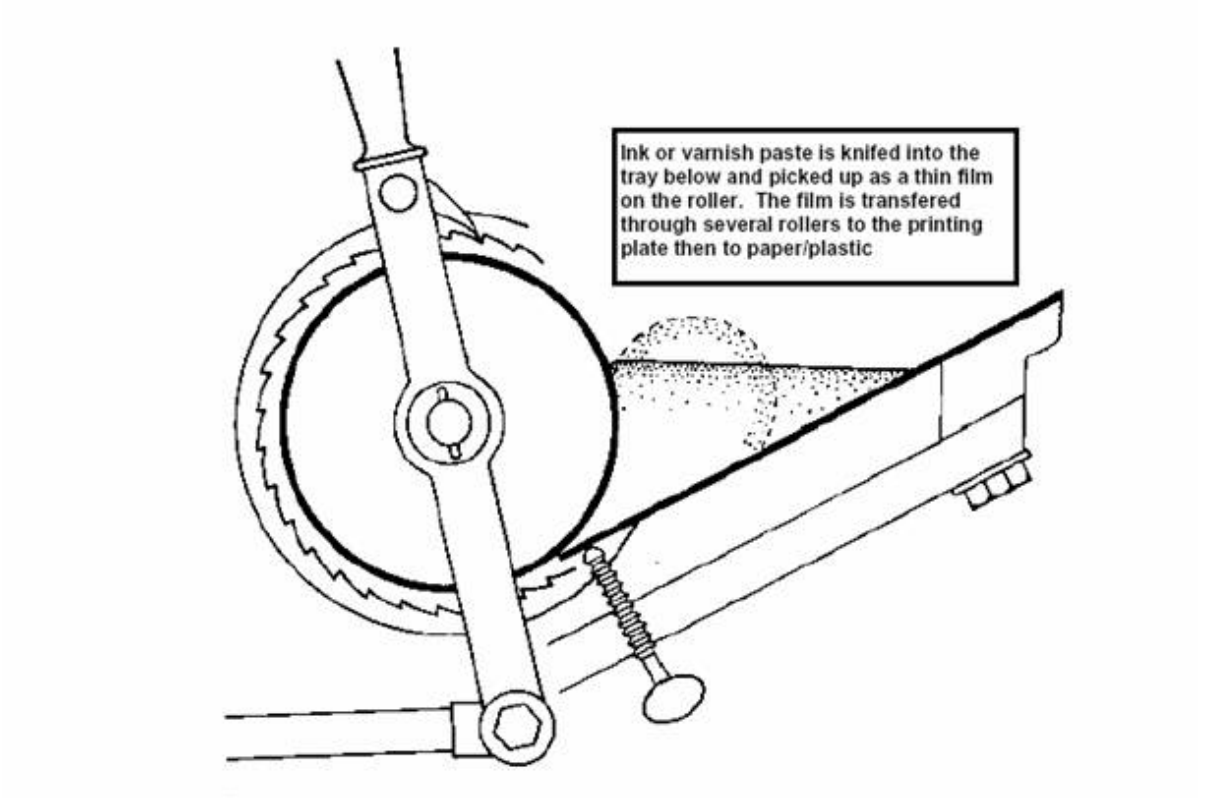
OPERATION DESCRIPTION
The notified polymer will not be manufactured in Australia. The majority of the notified polymer will be sold in finished inks as imported, but some blending may occur.

Small-scale manual blending may be performed on the ink containing the notified polymer using ink knives, primarily as a laboratory exercise.

However, it is expected that the bulk of blending would be by mechanical mixing and a three-roll mill.
The notified polymer will be added to a blending tank with other ink components and blended with a mechanical mixing blade.

After blending, the ink mixture containing the notified polymer will be poured from the blending tank into a three-roll mill to achieve an even consistency. The ink will then be funnelled into a container and transferred into product containers by manual filling with a tap.

The finished ink product containing the notified polymer will be used in industrial printing machines. The product will be scooped from its container onto ink feed ducts on the mechanical print press (see diagram below). The ink will then be distributed onto rollers, applied to a paper or plastic substrate and, exposed to a UV light source, curing it into a plastic film. This process is continuous and enclosed.



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)*
Ink formulation worker	4	2	260
Printing press worker	10	4	260
Industrial user (converter)	100	8	260

EXPOSURE DETAILS

Transport and Storage

Exposure to the notified polymer is unlikely during transportation and storage. Exposure may result where an accidental spill or leak from the container occurs.

Laboratory mixing and colour matching

Laboratory staff may be exposed to small quantities of the notified polymer (at up to >98%) from drips, spills and splashes via the dermal and ocular routes during manual mixing and colour matching with an ink knife. Laboratory staff are expected to wear safety goggles, gloves, protective overalls and barrier creams to minimise exposure. Inhalation exposure is likely to be minimal considering the high molecular weight and low vapour pressure of the notified polymer.

Ink formulation

Manual blending of the notified polymer (at up to >98%) with other ink components using an ink knife may result in dermal and ocular exposure.

Workers may be exposed to the notified polymer (at up to >98%) via the dermal and ocular routes from drips, spills and splashes during the charging of the blending vessel. Exposure may also result from splashes during milling using a water-cooled three-roll mill and during repackaging of the ink product into containers. Cleaning of the blending vessels using a high-pressure water washer may also result in dermal and ocular exposure. Inhalation exposure is likely to be minimal considering the high molecular weight, high viscosity and low vapour pressure of the notified polymer.

Workers are expected to wear safety goggles, protective gloves, protective overalls as well as apply barrier creams to limit the extent of exposure.

End use

There is potential for dermal and ocular exposure to inks containing the notified polymer during their end use in industrial printing applications. Converters may be exposed to ink containing the notified polymer at ~20% while using an ink knife to transfer the ink out of product containers and onto ink feed ducts on the printing plate (see diagram above). The printing and curing process will be carried out within a closed system, so exposure is expected to be minimal or negligible during these processes. Once cured onto the substrate, the notified polymer is expected to be covalently bound within the ink matrix and therefore unavailable to cause exposure.

Workers are expected to wear safety glasses, protective overalls and safety gloves, during the manual dispensing of inks, washing rollers and ducts and loading of empty drums into washing machines.

6.1.2. Public exposure

The public will not be exposed to the notified polymer in its imported forms except in the event of a transport accident.

The public will be exposed to printed paper or plastic containing the notified polymer. Once the ink is cured, the notified polymer is covalently bound in the ink matrix, and therefore dermal exposure to the notified polymer from contact with the printed media is not expected.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	oral LD50 >2000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation

Toxicokinetics, metabolism and distribution.
Based on its molecular weight (Mn >1000 Da), the notified polymer is not expected to be readily absorbed across biological membranes. However, the presence of ~20% of <1000 Da species, given the log Pow of ~2, may be absorbed at low levels. Dermal absorption is likely to be low.

Acute toxicity
The notified polymer was found to be of low acute oral toxicity (LD50 >2000 mg/kg bw). Significant acute dermal toxicity is not expected, as it is unlikely that it will readily cross the stratum corneum.

Irritation and Sensitisation
The notified polymer was tested for primary skin irritation and skin sensitisation. In rabbits, the observed primary irritation index score was 0.11 out of 8 and was therefore found to be slightly irritating. An eye irritation test was not submitted. However, based on the results of the skin irritation test, the potential for the notified polymer to cause eye irritation cannot be ruled out.

In the Guinea pig maximisation test, a dermal challenge with 25% notified substance did not cause any skin reactions. The notified polymer is not considered to be sensitising to skin.

Repeated Dose Toxicity
Information on toxicity studies conducted with a reactive monomer was received. In a 90-day repeat-dose study in rats, males dosed at 39 mg/kg/day and 202 mg/kg/day, as well as females dosed with 226 mg/kg/day displayed significant decreases in feed consumption and weight gain. Treated males and females had elevated serum alkaline phosphatase levels at the 1-, 2- and 3-month observations. These observations were considered attributable to treatment with the monomer.

At necropsy, a treatment-related decrease in mean absolute heart weight and a decrease in absolute and relative liver weight was observed in all dosed males and appeared to be treatment related.

However, given the monomer is a component of the notified polymer (Mn >1000 Da), the notified polymer is expected to exhibit lower repeat dose toxicity.

Genotoxicity
The *in vivo* mouse dominant lethal assay performed with a reactive monomer at doses of up to 2230 mg/kg/day exhibited low toxicity in mice (LD50 > 2230 mg/kg bw).

The notified polymer was not mutagenic to bacteria *in vitro*, under the conditions of the Ames test used at concentrations up to 5000 µg/plate.

In an *in vitro* test conducted using the mouse lymphoma L5178Y cell line on the reactive monomer, none of the treated cultures, in the presence or absence of metabolic activation exhibited a significant increase in mutant frequency.

In another *in vitro* test conducted on the reactive monomer, using the mouse BALB/3T3 cell line, all of the cultures treated at doses up to 0.078 mg/ml for 72 hours exhibited a slightly higher mean of transformation vs the control cultures. However, this difference was only statistically significant at one low dose level and no dose response was observed. Therefore, the monomer was considered non-transforming.

Overall, the notified polymer is not classified as mutagenic based on the results of *in vitro* tests on the notified polymer and reactive monomers.

Toxicity for reproduction
In the *in vivo* mouse dominant lethal assay conducted on the reactive monomer, males were dosed for 5 days with up to 2230 mg/kg/day. A slight decrease in fertility was observed in the 5th week post treatment. However, no other adverse effects were observed. Therefore, the reactive monomer was considered to be of low reproductive toxicity.

Classification
Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for*

Classifying Hazardous Substances [NOHSC: 1008 (2004)].

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

There is potential for dermal and ocular exposure to the notified polymer (at up to >98%) during blending processes, especially during manual blending with an ink knife. There is also potential for dermal and ocular exposure to ink containing the notified polymer at ~20% for converters while transferring the ink product from containers onto the printing presses.

As the notified polymer was not found to be a strong irritant or a sensitiser, the risk of the notified polymer causing these effects in workers is considered to be low. In addition the workers are expected to be wearing appropriate PPE, which would further minimise the risk.

Due to its expected low dermal absorption and low acute oral toxicity, systemic toxicity is not expected following repeated dermal exposure. Should absorption occur, any effects are expected to be minor given the molecular weight of the notified polymer (> 1000 Da) and the relatively high oral doses of the reactive monomer required to exhibit a toxic response in rats (≥ 39 mg/kg/day in males and ≥ 226 mg/kg/day in females).

Therefore, the risk to workers is not considered to pose an unreasonable risk to workers, based on the anticipated low exposure and low toxicity.

6.3.2. Public health

Members of the public will only be exposed to paper and plastic substrates in which the notified polymer will be bound within a cured polymeric matrix. Therefore, the risk is considered to be low, due to its expected low exposure and its expected low toxicity.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

There should be no release of notified polymer to the atmosphere during blending or repacking operations. Equipment is cleaned by high pressure hot water washing of the mixing pans, solvent washing for high speed stirrer, mill and mixing knives. Washing residues and used rags are sent for reprocessing and semi solid residue is collected for reprocessing by licensed waste processors.

RELEASE OF CHEMICAL FROM USE

The notified polymer is a component of printing ink used by commercial printers for packaging and labels. The ink will be supplied initially to one printer, and in future, to a number of printers.

The environmental release from accidental spillage will be minimal. The notified polymer will not pollute the air, any product lost to land should bind with soil and not migrate, and spills to water will not dissolve but disperse or settle as sediment. Contaminated product will be sent to a waste contractor for processing and disposal to landfill. The residue from cleaning equipment will not exceed more than 1%. The notified polymer will be used by industrial operators only.

There will be minimal environmental exposure during printing. No release to the atmosphere is expected during normal printing processes. The notified polymer will be used as a component of UV curable inks. Once these inks have been cured the notified polymer is expected to remain within the product matrices. Hence, the majority of the notified polymer will share the fate of the articles into which it is incorporated. It is anticipated that these will be disposed of to landfill or incinerated at the end of their useful lifetime. In landfill it is expected that the notified polymer will remain immobile within the ink matrix. Incineration of the notified polymer will result in the formation of water vapour and oxides of carbon and hydrochloric acid.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues remaining in the import containers (1-2%) will be disposed of either through metal recycling

companies or the controlled waste system (plastic cans) and be disposed of by incineration or washed and sent to landfill.

If product containing the notified polymer needs to be disposed of, this should be carried out by a licensed waste contractor. Contaminated packaging should be cleaned and recycled. Disposal must be accordance with local waste regulations.

7.1.2 Environmental fate

Under normal processing no release of the notified polymer to the atmosphere is likely. Residuals of the UV curable formulations (inks, coatings, and adhesives) will be polymerised (cured) by UV light to form an inert, solid matrix, which will not further enter the environment.

The notified polymer is moderately water-soluble. In landfill, the notified polymer is expected to degrade slowly by abiotic and biotic processes to oxides of carbon, hydrogen chloride and water. One part of the notified polymer is chlorinated and is likely to be persistent.

While environmental exposure is limited during ink use, the total import volume of the notified polymer will ultimately be disposed of in either landfill or be incinerated. The widespread use pattern indicates that landfills throughout Australia would receive the notified polymer bound into the ink matrix within steel and plastic containers and on paper products. The used ink containing the notified polymer would be expected to remain within the container unless breached. On paper the notified polymer will interact with other components to form a stable polymer matrix and, once dry, is expected to be immobile and not pose significant risk to the environment.

During recycling processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, ink detachment from the fibres, pulp brightness and the whiteness of paper. These aqueous wastes are expected to go to sewer. Very little of the notified polymer is expected to partition to the supernatant water which is released to the sewer. Sludge generated during the washing process is dried and incinerated or sent to landfill for disposal.

7.1.3 Predicted Environmental Concentration (PEC)

The release to the aquatic environment of the notified polymer is likely to be low. The following Predicted Environmental Concentration (PEC) can be estimated as a worst case on using 5% national release to sewer, presuming no removal due to partitioning out of the water column and no degradation:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment	
Total Annual Import/Manufactured Volume	100,000
Proportion expected to be released to sewer	5.000%
Annual quantity of chemical released to sewer	5,000
Days per year where release occurs	365
Daily chemical release	13.70
Water use	200.0
Population of Australia (Millions)	20.496
Removal within STP	0%
Daily effluent production	4,099
Dilution Factor - River	1.0
Dilution Factor - Ocean	10.0
PEC - River	3.34
PEC - Ocean	0.33

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical is summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*

Fish Toxicity	EC50 > 100 mg/L	The notified polymer is not toxic to fish up to the limit of water solubility.

7.2.1 Predicted No-Effect Concentration

One fish toxicity study has been provided indicating that the notified polymer is not toxic to fish with a LC50 >100 mg/L. Since only one test result is available an assessment factor of 1000 was used, thus giving a PNEC of >1 mg/L.

7.3. Environmental risk assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	3.34	100	0.03
Q - Ocean:	0.33	100	0.003

An estimated PEC/PNEC ratio for fresh water can be determined to be 0.03. Since this ratio is below 1 the risk to the aquatic environment due to the notified polymer is likely to be low.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

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

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and its reported use pattern, the notified polymer is not considered to pose a risk to the environment based on its reported use pattern.

Recommendations

REGULATORY CONTROLS

CONTROL MEASURES
Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced, as diluted for use, and in the imported ink products:
  - *Safety goggles*
  - *Protective gloves*

  Guidance in selection of personal protective equipment can be obtained from 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.

- Empty containers should be taken for local recycling, recovery or waste disposal.

Storage

- The following precautions should be taken regarding storage of the notified polymer:
  - *Keep containers tightly closed in a dry, cool and well-ventilated place.*

Emergency procedures

- Spills or accidental release of the notified polymer should not be allowed to enter surface water or sewer system.

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 polymer has a number-average molecular weight of less than 1000 Fa.

or

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

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Transition Glass Temperature 12°C

Method	In-house method.
Remarks	Test report not available.

Density 1 240 kg/m^3 at 20°C

Method	Flask Method. In-house method.
Remarks	Test report not available.

Water Solubility 0.0385 g/L at 20°C

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method. The sample was analysed by spectrophotometry.
Test Facility	Mader Kunstharze (2001)

n-Octanol Solubility 6.1g/L at 23°C

Method	EPA OPPTS 830.7550 (Partition Coefficient Shake flask method)
Remarks	Report available
Test Facility	Bodycote Materials Testing (2001)

Partition Coefficient (n-octanol/water) log Pow = 1.76.at 20°C

Method	US EPA 'Product Properties Test Guidelines' OPTTS 830.7550
Remarks	Partition Coefficient, n-Octanol/Water: shake flask method A standard flask method procedure was followed, with analysis by optical density.
Test Facility	Bodycote Materials Testing (2001)

Viscosity 100000 – 150000 mPa.s

Method	DIN 53019 (no further details available)
Remarks	Data source: MSDS

Flash Point >100°C at 1013 kPa

Method	In-house method.
Remarks	A screening test method was employed to ensure the product has a high flash point. Test report not available.

Autoignition temperature >320°C

Method	Differential Scanning Calorimetry (DSC).
Remarks	The notified polymer decomposed without polymerisation at temperatures >320°C.
Test Facility	Walter Mäder AG

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/HanBrl: WIST (SPF)
Vehicle	PEG 300; test substance was added as suspension.
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 per sex	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	No clinical signs or effects on body weight gain were observed.
Effects in Organs	No macroscopic findings were noted at the scheduled necropsy.
Remarks - Results	All animals survived to the scheduled necropsy. There were no remarkable body weight changes noted during the study.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	RCC Ltd (2001a)

B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer at 50% in PEG 300
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	PEG 300.
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.11	0	0	1	24 h	0
Oedema	0	0	0	0	0 h	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	Very slight erythema was observed in one male from 1 to 24 hours after treatment. One female animal also showed very slight erythema 1 hour after treatment. All reactions were reversible and had cleared by 48 hours after treatment. No signs of oedema were observed.
CONCLUSION	The notified polymer is slightly irritating to the skin.
TEST FACILITY	RCC Ltd (2001b)

B.3. Skin sensitisation

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 406 Skin Sensitisation – Maximisation Test
Species/Strain	Guinea pig/albino
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 5% (in 1:1 FCA/physiological saline) topical: 50% (in PEG 300)
MAIN STUDY	
Number of Animals	Test Group: 10 F Control Group: 5 F
INDUCTION PHASE	Induction Concentration: intradermal: 5% topical: 50%
Signs of Irritation	Discrete/patchy erythema was observed in 9/9 surviving animals (see below) at the 24- and 48-hour readings after topical induction with the test item at 50% in PEG 300. No such effects were observed in control animals treated with PEG 300 alone.
CHALLENGE PHASE	
1st challenge	topical: 25%
Remarks - Method	No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals showing skin reactions after challenge*	
		24 h	*48 h*
Test Group	25%	0/9	0/9
Control Group	25%	0/5	0/5

Remarks - Results	One animal of the test group was found dead on test day 10. At necropsy, no macroscopic findings were noted. The cause of death could not be established but was not considered to be related to treatment. There were no substance-related signs of toxicity during the study.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.
TEST FACILITY	RCC Ltd (2001c)

B.4. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure (Test 1)/Pre incubation procedure (Test 2)
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102.
Metabolic Activation System	6-napthoflavone/Phenobarbital-induced rat liver S9-mix
Concentration Range in Main Test	a) With metabolic activation: 33 - 5000 µg/plate b) Without metabolic activation: 33 - 5000 µg/plate
Vehicle	DMSO
Remarks - Method	2-Aminoanthracene was used as the only positive control for assays with metabolic activation. The test guideline advises against this.

RESULTS

Remarks - Results	The test material was tested up to the maximum recommended dose level of 5000 µg/plate. No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation. The positive controls induced marked increases in the frequency of revertant colonies, confirming the activity of the S9-mix and the sensitivity of the bacterial strains.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	RCC Ltd (2001d)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test -Static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - Static.
Species	*Poecilia reticulata*
Exposure Period	96 hrs
Auxiliary Solvent	None
Water Hardness	1.53-2.78 mg $CaCO_3$/L
Analytical Monitoring	Not conducted
Remarks – Method	The nominal test concentration of 100 mg/L was prepared by dilution or, in case of poor solubility, by adding the notified polymer directly to the test medium.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*				
		1 h	*24 h*	*48 h*	*72 h*	*96 h*
(Control)	7	0	0	0	0	0
100	7	0	0	1	0	0

LC50	> 100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	The No Observed Effect Concentration (NOEC) was 100 mg/L since the one fish that died was considered not to represent a significant effect. At the applied nominal test concentration the notified polymer was not dissolved. No chemical analysis of the notified polymer was conducted. Other toxic effects than mortality, e.g. loss of coordination, hypo- or hyperactivity and swimming on the back, were not observed.
CONCLUSION	The notified polymer is not toxic to *Poecilia reticulata* up to limit of its water solubility.
TEST FACILITY	BMG Engineering AG (2001)

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