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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Y-17112

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

Y-17112

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Momentive Performance Materials Australia Pty Ltd (ABN 47 105 651 063)
Level 2, 600 Victoria Street
RICHMOND VIC 3121

NOTIFICATION CATEGORY

Standard: Synthetic Polymer with Mn < 1000 Da (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical name, Molecular formula, Structural formula, Molecular weight, Spectral data, Methods of detection and determination, Residual Monomers, Purity, Import volume, Use concentrations, Details of analogue and Physical and chemical properties.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Melting point, Boiling point, Vapour pressure, Hydrolysis as a function of pH, Adsorption/Desorption, Flammability, Autoignition temperature, Explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

No

NOTIFICATION IN OTHER COUNTRIES

USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Y-17112

OTHER NAME(S)

Silicone polyether copolymer

MOLECULAR WEIGHT

< 1000 Da

ANALYTICAL DATA

Reference NMR, IR and HPLC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 70%

ADDITIVES/ADJUVANTS *None*

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Light yellow liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-1 °C	MSDS
Boiling Point	449 °C	Estimated (EPIWIN v3.20))
Density	1000 kg/m ³ at 25°C	MSDS (estimated)
Vapour Pressure	2.3x10 ⁻⁹ kPa	Estimated (EPIWIN v3.20)
Water Solubility	0.087 g/L	Measured
Hydrolysis as a Function of pH	Not determined	The rate of hydrolysis is expected to be slow (half-life more than a year) based on the structure and intended use.
Partition Coefficient (n-octanol/water)	log Pow = 4.9	Measured (HPLC method)
Adsorption/Desorption	Not determined	The notified polymer is a wetting agent classed as a superspreader, and can therefore be expected to sorb to soils.
Dissociation Constant	Not determined	No dissociable groups.
Flash Point	127°C at 103 kPa (closed cup)	Measured
Flammability	Not expected to be highly flammable	Estimated from measured flash point.
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosophores

DISCUSSION OF PROPERTIES

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

The notified polymer is classed as a “superspreader”, a chemical adjuvant that enhance spreading of aqueous formulations on solid surfaces to far greater values than conventional surfactants.

Based on the measured flash point, the notified polymer is not classified as flammable but would be considered to be a C1 combustible liquid [NOHSC:1015(2001)].

Reactivity

The notified polymer is predicted to be stable under normal conditions of use.

Dangerous Goods classification

Based on the available data the notified polymer is classified as follows according to the Australian Dangerous Goods Code (FORS, 1998):

Class 9 Miscellaneous (environmentally hazardous substance)

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be introduced in the neat form (at > 70% purity) or as a component of household care products (at < 0.5%) including dishwashing detergents, hard-surface cleaners and carpet cleaners, and surface coatings (at < 3%).

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

Year	1	2	3	4	5
Tonnes	< 5	< 5	< 5	< 7	< 10

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING

The notified polymer will be imported by sea and transported from the wharf by road to the notifiers warehouse as the neat form in 20 L and 200 L drums, and in household care products and surface cleaners in ready-to-use packaging (0.5-5 L).

USE

The notified polymer will be used as a wetting agent in household care products at concentrations of < 0.5% (50% of the import volume) including dishwashing detergents, hard-surface cleaners and carpet cleaners, and as a wetting and levelling agent in water-based surface coatings at concentrations of < 3% (50% of the import volume) for application onto metal, glass, wood and plastic substrates..

OPERATION DESCRIPTION

Re-packing

On rare occasions, the neat form of the notified polymer (at > 70%) will be re-packed from the 200 L drums into 2 L containers for customer evaluation. The re-packing operation will use a closed dispensing process with general air extraction in the immediate area, backed by localised extraction where the operator is loading and unloading the small containers at the dispensing point.

Formulation

The notified polymer (at > 70%) will be meter fed from the import drums via lance and pump to enclosed blending vessels, where it will be mixed with water and other ingredients to form the desired end-use household care products containing < 0.5% of the notified polymer. These products will then be directly pumped from the blending vessels to 0.5 L and 1 L containers by an automated filling process.

End use

Hard-surface cleaners and carpet cleaners containing the notified polymer (at < 0.5%) will likely be applied by spray application and wiped off using a cloth. Dishwashing products containing the notified polymer (at < 0.5%) will be used in automatic dishwashers and for manual dishwashing.

There will be no reformulation of the imported surface coating products containing the notified polymer at < 3%. These products will be applied to surfaces by spray, brush or roller by professional contractors and tradespeople. Spray applications are expected to be applied in a spray booth with local exhaust ventilation.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	1	0.3	10
Formulation	2	1	20
QC technicians	1	0.6	20
Repackers	1	0.5	20

EXPOSURE DETAILS

Dermal exposure to the notified polymer (at > 70%) may occur when connecting and disconnecting transfer lines to the blending vessels and through contact with drips from the lance when it is transferred from one drum to another. Dermal exposure to the notified polymer (at < 0.5%) may occur during routine clean-up operations, when taking samples of blended products by technicians for quality control testing and when connecting and disconnecting transfer lines for package filling.

Inhalation exposure is not likely as the notified polymer has low volatility and blending occurs in enclosed vessels. Local exhaust ventilation will also be used.

Where dermal exposure to the notified polymer is likely, PPE including gloves and safety glasses are expected to be worn by workers to minimise exposure.

Once the household products (containing the notified polymer at < 0.5%) are packaged for distribution, no further worker exposure is expected from contact with the sealed packages. However, use of the products by commercial users is possible, and would be similar to the pattern of public exposure. The level of PPE used is likely to vary and would include gloves in many cases.

Dermal and ocular exposure may occur when applying the surface coating products (containing the notified polymer at < 3%) by brush or roller and when cleaning the application equipment with water. However, exposure will be minimised by workers wearing personal protective equipment (PPE) such as coveralls, goggles, and impervious gloves.

Inhalation exposure may occur during spray application. However inhalation exposure should be minimised if spray painting is conducted as expected in spray booths with local exhaust ventilation.

6.1.2. Public exposure

Household care products including dishwashing liquids, hard-surface cleaners and carpet cleaners, containing up to 0.5% of the notified polymer will be used widely by consumers.

The main exposure to the notified polymer is likely to be dermal, when hand washing dishes in water containing the product or washing hands with the neat dishwashing liquid containing the notified polymer (at < 0.5%). In addition dermal exposure may also occur to the notified polymer (at < 0.5%) when applying the surface cleaners through drips and spills, and when cleaning the applied surfaces with a cloth.

Inhalation exposure may occur due to the formation of aerosols when applying the hard-surface cleaners or carpet cleaners by spray application. Inhalation exposure is unlikely from the dishwashing liquid or from water containing it, as the chemical has low volatility and aerosols are unlikely to be formed.

Systemic exposure to the notified chemical through inhalation of aerosols and mists is estimated to be 1.6×10^{-5} mg/L bw/day. This is based on the following assumptions (SDA, 2005) and a bodyweight of 65.4 kg:

Use frequency of trigger spray cleaners	1 use/day
Respirable product conc. in breathing zone	0.72 mg/m ³
Inhalation rate	1.0 m ³ /hr
Exposure duration	0.25 hr
Bioavailable fraction	100%

Oral exposure could occur from ingestion of residues of the dishwashing liquid remaining on plates and utensils.

The worst case systemic exposure to the notified chemical via the oral route through ingestion of residual chemical remaining on non-rinsed dinnerware is estimated to be 2.5×10^{-4} mg/kg bw/day. This is based on the following assumptions (HERA, 2005) and a bodyweight of 65.4 kg:

Area of dishes/eating utensils in daily contact with food	5400 cm ²
Amount of dishwashing water retained on non-rinsed dinnerware	5.5×10^{-4} ml/cm ²
Concentration of dishwashing liquid	0.001 g/cm ³
Concentration of notified chemical in liquid detergent	0.5%
Fraction ingested	100%

It is expected that some consumers would wear gloves while using the household care products, and others would not.

6.2. Human health effects assessment

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

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 = 500 mg/kg bw; harmful
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	LC50 = 2 mg/L/4 hour; harmful (<i>analogue</i>)
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 14 days	NOAEL < 97 mg/kg bw/day (<i>analogue</i>)
Rat, repeat dose dermal toxicity – 11 days	NOAEL > 1551 mg/kg bw/day (<i>analogue</i>)
Rat, repeat dose inhalation toxicity – 9 days	NOEL < 0.025 mg/L bw/day (<i>analogue</i>)
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Mammalian Chromosome Aberration Test (Chinese Hamster ovary cells)	non genotoxic (<i>analogue</i>)
Genotoxicity – in vitro Mammalian Cell Gene Mutation Test (Chinese Hamster ovary cells)	non-genotoxic (<i>analogue</i>)
Genotoxicity – in vivo Mouse Micronucleus Test	non genotoxic (<i>analogue</i>)

Toxicokinetics, metabolism and distribution

Given its high lipophilicity and low water solubility, the notified polymer is expected to penetrate the stratum corneum but transfer into the hydrophilic epidermis layer is not expected, hence systemic toxicity is unlikely via the dermal route.

Although the notified polymer has a low water solubility, it is a surfactant with superspreading capabilities and as such is expected to be attracted to and disperse along the walls of the GI tract, a property that should assist in the passive uptake of the notified polymer, hence systemic toxicity via the oral route is a possibility.

However, given the low vapour pressure of the notified polymer toxicity by inhalation is unlikely except where mists or aerosols are formed.

Acute toxicity

The notified polymer has a low acute dermal toxicity but is considered harmful if swallowed based on acute oral toxicity studies in rats (LD50 = 500 mg/kg bw). Both animals dosed at 2000 mg/kg bw died within 5 hours post-dose. However no treatment related signs of toxicity were observed in six animals dosed at 300 mg/kg bw.

Based on the results of the acute oral toxicity study the notified polymer is classified as ‘Harmful if swallowed (R22)’ according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Acute inhalation

The notified polymer is considered to be toxic (LC50 2 mg/L 4h) by inhalation based on a 4-hour whole body aerosol exposure on rats in a study conducted on an acceptable analogue of the notified polymer at exposure concentrations of 0.26, 1.1 and 2.0 mg/L. Five animals out of 10 tested died or were euthanized when exposed to 2.0 mg/L and 2 out of 10 died or were euthanized when exposed to 1.1 mg/L.

Based on the results of the acute inhalation toxicity study the acceptable analogue of the notified polymer is classified as ‘Harmful by inhalation (R20)’ according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Irritation and Sensitisation

Based on a test conducted in rabbits the notified polymer is not considered a skin irritant. However, the notified polymer did cause some irritation when tested on the eyes of rabbits but was not severe enough to be classified for eye irritation according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. Irritation effects observed included conjunctiva redness and swelling that persisted for up to 6 days. All symptoms were resolved after 7 days.

The notified polymer is not considered to be a skin sensitizer based on the results of a guinea pig maximisation

test study.

Repeated Dose Toxicity

Oral: In a 14-day repeat dose study conducted on rats fed with an acceptable analogue of the notified polymer in their diets, treatment related effects were observed at all dose levels tested. Hence the no observed adverse effect level NO(A)EL can not be established but can be considered as < 97 mg/kg bw/day based on the lowest dose tested. However at this lowest dose, biological significant effects were minimal in nature, and were observed only in the thyroid gland, testes and ovaries. At higher dose levels effects upon body weight, food and water consumption, hematologic and clinical chemistry parameters and microscopic changes in testes, ovaries and thyroid glands were observed.

Dermal: No treatment related systemic effects were observed in a repeated dose dermal toxicity study (6 hours/day for 9 out of 11 days) on an acceptable analogue of the notified polymer at all dose levels studied. As such the No Observed (Adverse) Effect Level (NO(A)EL) was established as > 1551 mg/kg bw/day.

Inhalation: In a 9-day whole of body repeat dose inhalation study conducted in rats exposed to an aerosol of the notified polymer at 0.025, 0.08 (mid) and 0.25 (high) mg/L for 6 hours/day, treatment related effects were observed at all dose levels. Hence the NO(A)EL can not be established but can be considered as < 0.025mg/L bw/day based on the lowest exposure concentration tested. However, at this exposure concentration there was a low incidence of ocular opacity (1 animal) and rales (2 males and 2 females one hour following exposure on study days 0, 1 or 2), and a single occurrence of mild necrosis in the nasal respiratory epithelium. Two mortalities out of 20 animals tested were observed in the high dose group (high dose). The notified polymer also caused clinical signs of toxicity (particularly rales, but also ocular opacities) (mid and high dose), inhibition of body weight gain and food consumption (mid and high dose), changes in clinical pathology (high dose), decreased thymus gland weights (high dose) and microscopic lesions in the nasal cavity (mid and high dose).

Mutagenicity

The notified polymer was found to be not mutagenic in bacteria under the conditions of the Ames test used. In addition, an acceptable analogue of the notified polymer did not induce chromosomal aberrations or mutations in mammalian cells. On the basis of weight of evidence the notified polymer is not expected to be genotoxic.

Health hazard classification

Based on the result of the acute oral toxicity study, the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:

- R22 Harmful if swallowed

In addition based on the result of the acute inhalation toxicity study conducted on an acceptable analogue of the notified polymer, the notified polymer should be considered as if it is classified as:

- R20 Harmful by inhalation

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Based on the available data, the notified polymer is considered harmful by the oral and inhalation routes. The notified polymer also has some potential for eye irritation. Hazards from dermal exposure to the notified polymer are not expected.

Given the low vapour pressure of the notified polymer toxicity by inhalation is unlikely except where mists or aerosols are formed. Exposure to aerosols containing the notified polymer at < 0.5% may occur during blending and when commercial cleaners apply the hard-surface cleaners and carpet cleaners using trigger-based spray applicators. In addition inhalation exposure may occur when applying surface coatings containing the notified polymer at < 3% by spray application.

During blending inhalation exposure should be minimised through the expected use of enclosed reaction vessels and local exhaust ventilation (LEV). Similarly, inhalation exposure during spray application of surface coatings should be minimised as they are expected to occur in a spray booth with LEV. The use of respiratory protection would further reduce exposure.

The risk to commercial cleaners from inhalation exposure to the notified polymer is expected to be similar to the risk posed to the public from use of trigger based household cleaners (see Public Health). Based on the known systemic toxicity of the notified polymer and estimated margin of exposure (MOE), the risk to workers health after use of the cleaning products containing the notified polymer at < 0.5% is not considered unacceptable.

Eye irritation may occur when handling the neat form of the notified polymer (at > 70%). The expected use of safety goggles should minimise this risk.

Overall, given the expected engineering controls in place and use of PPE, the risk to the health of workers to the notified polymer introduced and used as described is not considered unacceptable.

6.3.2. Public health

Inhalation exposure may occur when the public apply household care products such as surface cleaners and carpet cleaners by trigger-based spray applicators.

Considering the systemic exposure to the notified polymer through inhalation of aerosols and mists from use of trigger-based household cleaning products (surface cleaners and carpet cleaners) containing the notified polymer at 0.5% is estimated to be 1.6×10^{-5} mg/L bw/day (see Sec. 6.1.2). Using the NOEL of 0.025 mg/L bw/day from a 9-day inhalation toxicity study for an analogue of the notified polymer, a MOE of >1000 is calculated.

Exposure by the oral route may be possible from ingestion of any residual notified polymer remaining on dinnerware after washing. Considering the systemic exposure to the notified polymer via the oral route from ingestion of residual notified polymer on non-rinsed dinnerware is estimated to be 2.5×10^{-4} mg/kg bw/day (see Sec. 6.1.2), using the NOEL of 97 mg/kg bw/day from a 14-day oral toxicity study conducted on an analogue of the notified polymer, a MOE of >> 1000 is calculated.

MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. The MOE is based on conservative assumptions (e.g. 100% bioavailability) and therefore likely to overestimate the risk.

Overall, the risk to the public from the use of household products containing the notified polymer at up to 0.5% is not considered to be unacceptable based on the toxicity data provided and the estimated MOE.

Given the public will only be exposed to products containing low concentrations of the notified polymer (< 0.5%) the risk of eye irritation is not expected.

Overall, the risk to public health from use of products containing the notified polymer at up to 0.5% is not considered unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

No significant releases are expected from local formulation as production areas will be contained and liquid from equipment and drum cleaning will be used in the next batch of product. Waste from spillage will be salvaged for reuse or adsorbed and collected for landfill disposal via a licensed contractor. It is expected that less than 1% will be wasted in this way.

RELEASE OF CHEMICAL FROM USE

In general, cleaning agents containing the notified polymer will be wiped off on cloths that are either rinsed to sewer or disposed of with household rubbish. When used for dishwashing, the notified polymer will be washed to sewer.

When used as an additive in coatings, the notified polymer will be incorporated into the coating. It is non-reactive and will not be covalently bound to the cured polymer matrix, but will not be bioavailable because of its containment in the coating. Small amounts of the cured paint will be collected as overspray when application occurs in spray booths, and will be sent to landfill. Similarly, coated articles are likely to be sent to landfill at the end of their useful life. Minor amounts may be washed to sewer during cleaning of application equipment.

RELEASE OF CHEMICAL FROM DISPOSAL

Small amounts of the notified polymer are likely to be disposed of to landfill as drum residues and waste material from spills. Cured coatings containing the notified polymer will also be sent to landfill, either as overspray or on discarded articles.

7.1.2 Environmental fate

Substantial removal with sludge during sewage treatment can be assumed because of its superspreading properties. The notified polymer is hydrolytically stable and not readily biodegradable, but should undergo slow degradation in landfills and the environment. It is not expected to bioaccumulate because of its molecular weight and surface activity. For the details of the environmental fate studies, please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

The PEC has been estimated as tabulated below based on an annual import volume of 7000 kg and worst case assumptions, namely 50% use in applications such as dishwashing formulations that entail washing to sewer, and transfer of 100% through sewage treatment works into receiving waters. Note that this scenario is used as a conservative basis for risk assessment, and will overestimate the environmental exposure since only small amounts will be washed to sewer when the notified polymer is used in surface coatings. The assumption of complete passage through sewage treatment works is an overestimate as the notified polymer is surface active and can be expected to undergo significant removal during sewage treatment by sorption to sludge.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	7000	kg/year
Proportion expected to be released to sewer	0.5	
Annual quantity of chemical released to sewer	3500	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	9.6	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.374	million
Removal within STP	0%	
Daily effluent production:	4,275	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	2.2	µg/L
PEC - Ocean:	0.22	µg/L

7.2. Environmental effects assessment

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

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	LC50 = 2.94 mg/L	Toxic
Daphnia Toxicity	EC50 = 4.8 mg/L	Toxic
Algal Toxicity	EC50 = 6.79 mg/L	Toxic

The results from aquatic toxicity testing indicate that the notified polymer is toxic to aquatic life. All results are expressed as nominal concentrations, which were confirmed by DOC analysis to have been maintained throughout the test.

7.2.1 Predicted No-Effect Concentration

The PNEC can be determined by application of an assessment factor of 100 to the endpoints obtained in the most sensitive aquatic species from three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Median acute lethal concentration in fish	2.9	mg/L
Assessment Factor	100	
PNEC:	29	µg/L

7.3. Environmental risk assessment

Risk Quotients can be calculated as tabulated below.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	2.2	29	0.08
Q - Ocean	0.22	29	0.01

The notified polymer is not expected to pose a risk to the environment, as the estimated freshwater and marine risk quotients are well below unity.

Extrapolating from the above calculations, and using the same assumptions and scenario, the maximum import volume limit for cleaning applications that maintains a Q value ≤ 1 is shown in the following table:

<i>Secondary Notification Limit Volume</i>	<i>Limit (Max)</i>	<i>Limit (Practical)</i>
Q - River:	46138 kg/yr	46,000 kg/yr
Q - Ocean:	461,380 kg/yr	460,000 kg/yr

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] with the following risk phrases:

- R22 Harmful if swallowed

In addition based on the result of the acute inhalation toxicity study conducted on an acceptable analogue of the notified polymer, the notified polymer should be considered as though classified as:

- R20 Harmful by inhalation

and

As a comparison only, 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.

	<i>Hazard category</i>	<i>Hazard statement</i>
Health		
Acute (oral)	4	Harmful if swallowed
Acute (inhalation)	2	Fatal if inhaled
Environment		
Acute	2	Toxic to aquatic life
Chronic	2	Toxic to aquatic life with long lasting effects

Human health risk assessment

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

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

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose a 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:
 - R22 Harmful if swallowed
- Use the following risk phrases for products/mixtures containing the notified polymer:
 - Conc \geq 25%: R22

In addition:

- The introducers of the notified polymer should consider the following health hazard classification:
 - R20: Harmful by inhalation
- Use the following risk phrases for products/mixtures containing the notified polymer:
 - \geq 25%: R20

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified polymer during formulation:
 - Local exhaust ventilation
 - Enclosed blending vessels
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid aerosol formation
 - Avoid contact with eyes when introduced in neat form
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced in the neat form:
 - Safety goggles
 - Respiratory protection

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

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

Disposal

- The notified polymer should be incinerated in an appropriate incinerator equipped with exhaust gas cleaning if available or be disposed of by landfill.

Emergency procedures

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

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified 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(2) of the Act; if
 - the function or use of the chemical has changed from a wetting agent for household care cleaning products at concentrations of < 0.5% and surface coatings at concentrations of < 3%, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 10 tonnes per annum, or is likely to increase, significantly;
 - if the chemical 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.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet

The MSDS of 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.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 0.087 g/L

Method OECD TG 105 Water Solubility.
 Remarks Flask Method. Study not conducted to GLP.
 The notified polymer (0.75 g) was vigorously shaken for 10 minutes in 200 mL water, forming a slightly hazy dispersion, and analysed by reverse-phase HPLC after settling and triple filtration through 0.2 micron syringe filters. Note that the test material contained unreacted polyether.
 Test Facility Momentive Performance (2008a)

Hydrolysis as a Function of pH

Method OECD TG 111 Hydrolysis as a Function of pH.

<i>pH</i>	<i>T</i> (°C)	<i>t</i> _{1/2}
4	50	> 1 year
7	50	> 1 year
9	50	> 1 year

Remarks Preliminary test only, on the analogue substance Silwet L-77. Details are unclear as the test report was written in Portuguese and no English translation was provided. It is assumed that the notified polymer is hydrolytically stable, as might be expected from its chemical structure and intended use pattern.
 Test Facility TASQA (1994).

Partition Coefficient (n-octanol/water) log Pow = 4.9

Method OECD TG 117 Partition Coefficient (n-octanol/water).
 Remarks HPLC Method. Study not conducted to GLP.
 The notified polymer was determined to have a log Pow ranging from 4.1 to 5.7 due to the wide elution range. The majority of the notified polymer had a log Pow of 4.9. Note that the test material contained unreacted polyether.
 Test Facility Momentive Performance (2008b)

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/HsdRccHan:WIST (Full-Barrier)
Vehicle	Cotton seed oil
Remarks - Method	No significant protocol deviations

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	2F	2000	2/2
2	3F	300	0/3
3	3F	300	0/3

LD50	LD50 = 500 mg/kg bw
Signs of Toxicity	In the animals dosed at 2000 mg/kg bw, both animals died within 5 hours post-dose. No treatment related signs of toxicity were observed in the animals dosed at 300 mg/kg bw.
Effects in Organs	No treatment related effects were observed in any of the animals dosed at 300 mg/kg bw. Residual liquid of the test substance was found in the stomach of the animals dosed at 2000 mg/kg bw.
Remarks - Results	

CONCLUSION	The notified polymer is harmful via the oral route.
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TEST FACILITY	BSL Bioservice (2006a)
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B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rat/HsdRccHan:WIST (Full-Barrier)
Vehicle	None
Type of dressing	Occlusive
Remarks - Method	No significant protocol deviations

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5M	2000	0
2	5F	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	No treatment related effects observed
Signs of Toxicity - Systemic	No treatment related effects observed
Effects in Organs	No treatment related effects observed
Remarks - Results	No deaths occurred

CONCLUSION	The notified polymer is of low toxicity via the dermal route.
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TEST FACILITY	BSL Bioservice (2006b)
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B.3. Acute toxicity – inhalation

TEST SUBSTANCE	Acceptable analogue of notified polymer
METHOD	OECD TG 403 Acute Inhalation Toxicity.
Species/Strain	Albino Rat/Crl:CD®BR
Vehicle	None
Method of Exposure	Whole body (aerosol)
Exposure Period	Post exposure observation period: 14 days
Remarks - Method	4 hours
	No significant protocol deviations.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Concentration mg/L</i>	<i>Mortality</i>
1	5M/5F	0.26	0
2	5M/5F	1.1	1M/1F
3	5M/5F	2.0	2M/3F

LC50 2 mg/L/ 4 hours

Signs of Toxicity Seven animals out of thirty animals exposed either died or were euthanized for humane reasons during the study. On Day 3, one female was found dead and one male was euthanized in the 1.1 mg/L group. In the 2.0 mg/L group, two females were found dead on Day 3 and one was euthanized on Day 5. Two males were euthanized on Day 4 in the 2.0 mg/L group.

All animals at each dose tested showed clinical signs of toxicity to varying degrees during the observation period including matting of various areas of the body and rales, the number of incidence of which increased with increasing dose. Corneal opacity occurred in 9 animals in the 1.1 and 2.0 mg/L group.

All the animals in the 1.1 and 2.0 mg/L groups lost 10 to 70 grams from the first day of exposure to Day 3. All animals that survived recovered to or surpassed their initial body weights by Day 14.

Effects in Organs

No abnormal findings were noted in any animals in the 0.26 mg/L group. All animals that were found dead or were euthanized had darkened intestines, distension of the intestines, bilateral ocular opacity, white areas in the liver, mottled lungs, and various stomach abnormalities. Findings for animals that survived to the scheduled necropsy included four animals with hair loss on various locations (one 1.1 mg/L female; one male and two females in the 2.0 mg/L group), ocular opacity (one male and one female in the 2.0 mg/L group), and one rat with dark red areas in the lungs (1.1 mg/L).

Remarks - Results

The LC50 of the analogue polymer was determined to be 2.0 mg/L when male and female albino rats were exposed for a single, four-hour period under the conditions of the study.

CONCLUSION

Based on the results of the acceptable analogue of the notified polymer, the notified polymer is expected to be harmful via inhalation.

TEST FACILITY

WIL Research Laboratories (1995a)

B.4. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

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

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

Remarks - Results	No irritation effects were observed
CONCLUSION	The notified polymer is non-irritating to the skin.
TEST FACILITY	BSL Bioservice (2006c)

B.5. Irritation – eye

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	7 days
Remarks - Method	No significant protocol deviations

RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum</i> <i>Value</i>	<i>Maximum Duration</i> <i>of Any Effect</i>	<i>Maximum Value at End</i> <i>of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	2.0	2.0	2.0	2	6 days	0
<i>Conjunctiva: chemosis</i>	1.0	1.3	1.0	2	5 days	0
<i>Conjunctiva: discharge</i>	0	0	0.3	3 (1 hr)	24 hr	0
<i>Corneal opacity</i>	0.7	0.3	0.3	1	5 days	0
<i>Iridial inflammation</i>	1.0	0	0.3	1	5 days	0

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

Remarks - Results	<p>Redness of the conjunctiva (Grade 2) was observed in all animals at 24-hours, 48-hours and 72-hours after treatment. This reaction had completely resolved in all animals by Day 7.</p> <p>Some swelling of the conjunctiva was observed in all animals at 24-hours, 48-hours and 72-hours after treatment with one animal experiencing obvious swelling at the 24-hour observation period. The swelling had completely resolved in all animals by Day 6.</p> <p>Conjunctival discharge was observed in all animals after 1-hour and was completely resolved by Day 2.</p>
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Slight corneal opacity and iridial inflammation was observed in all animals. These reactions had completely resolved by Day 6.

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY BSL Bioservice (2006d)

B.6. Skin sensitisation

TEST SUBSTANCE Notified polymer

METHOD OECD TG 406 Skin Sensitisation - GPMT

Species/Strain Guinea pig/Hsd Poc : DH (Full-Barrier)

PRELIMINARY STUDY Maximum Non-irritating Concentration:

intradermal: 0.1% v/v isotonic saline NaCl (0.9%)

topical: 50% v/v isotonic saline NaCl (0.9%)

MAIN STUDY

Number of Animals

Test Group: 10

Control Group: 5

INDUCTION PHASE

Induction Concentration:

intradermal: 0.25% v/v isotonic saline NaCl (0.9%)

topical: 100%

Signs of Irritation

intradermal: slight erythema was observed in most test animals at sites receiving the notified polymer (0.25% v/v). Slight erythema was also observed in some control animals receiving the saline solution for washing only.

topical: slight erythema was observed after topical application (50% v/v) in 4 of 10 test animals immediately after patch removal. No signs of irritation were observed in any of the remaining test and control animals.

CHALLENGE PHASE

1st challenge

topical: 50% v/v isotonic saline NaCl (0.9%)

RESULTS

Remarks - Results

There were no dermal reactions observed in any of the test or control animals following challenge.

CONCLUSION

There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

TEST FACILITY

BSL Bioservice (2007)

B.7. Repeat dose toxicity

TEST SUBSTANCE Acceptable analogue of notified polymer

METHOD 14-day Oral Toxicity Study in Rodents.

Species/Strain Rat/Fischer 344

Route of Administration Oral – diet

Exposure Information Total exposure days: 14 days

Dose regimen: 7 days per week

Post-exposure observation period: 28 days

Vehicle

None

Remarks - Method

The protocol is similar to the OECD TG407 except for total exposure days (OECD TG 407 has 28 days).

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw/day</i>	<i>Mortality</i>
control	15M/15F	0	0
low dose	10M/10F	96.5(M);98.8(F)	0
mid 1 dose	10M/10F	706.3(M);751.6(F)	0
mid 2 dose	10M/10F	1262.3(M);1384.9(F)	0
high dose	10M/10F	1577.0(M);1791.2(F)	0
control recovery	5M/5F	0	0
high dose recovery	5M/5F	1577.0(M);1791.2(F)	0

Mortality and Time to Death

No mortalities were observed at any dose group.

Clinical Observations

Body weights: During the dosing period in the mid and high dose group for both males and females, there was an apparent dose-related decrease in absolute body weight and body weight gain. This trend persisted during the recovery period. The smallest body weight gain was observed in the high dose group. However, no effects on body weight were observed in the low dose group.

Food and water consumption:

Moderate decreases in food consumption was noted in both males and females in the mid and high dose groups throughout the study. Slight reduction in water consumption was noted in both males and females in the mid and high dose groups during the first two weeks of dosing.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology

Moderate dose-related decreases in reticulocytes and small dose-related decreases in platelets were noted in males and females in the mid and high dose groups at week 2. Some changes in hematologic parameters in both sexes tended to persist at the end of the study period suggesting an effect upon the erythron which may include changes in the production of platelets and erythrocytes.

Clinical chemistry

In males, urea nitrogen (mid 2 and high) was increased while phosphorus (mid 2 and high) and potassium (mid and high) was decreased at week 2. In females, urea nitrogen was increased in the high dose group and phosphorus was decreased in all dose groups at week 2 suggesting effects upon the kidney. Moderate decreases in serum enzyme activity and protein fraction changes in both males and females associated with increased protein clearance may also indicate effects upon the kidney, such as functional changes in this organ. At week 2 in the mid and high dose groups (male and female), aspartate aminotransferase was decreased. Alanine aminotransferase and alkaline phosphatase (ALK) were moderately decreased in males in the mid and high dose groups. Lactate dehydrogenase (LDH) was reduced in males in all dose groups. LDH was reduced in females (mid 2 and high) at week 2, while ALK was decreased in the mid and high dose groups at week 2.

Urinalysis

Evidence for functional changes in the kidney were also noted in the urinalysis data. In males, urine volume increased at week 2 in the low, mid 1 and high dose groups with no increase in water consumption suggesting a loss of urine concentrating ability. Small decreases in urine creatine and calculated creatine clearance were noted in males from the mid and high dose groups. Urine N-acetyl-β-D-glucosaminidase was increased in males in the mid and high dose groups at week 2.

Effects in Organs

Moderate organ weight increases in the liver and thyroid glands were observed in males and females in the mid and high dose groups. Minimal increases were observed in the low dose group. The liver and thyroid gland increases were resolved by week 6. The study authors suggest that these weight changes may indicate an adaptive change in the organ resulting in up-regulation of xenobiotic metabolising enzymes, which dissipated upon removal of the test substance during the recovery period.

Absolute testes weights were markedly reduced in all dose groups at week 2 that persisted until week 6. In females in the mid and high dose groups, spleen and ovary weights were decreased at week 2. At week 6, no differences in ovary weight were noted while spleen weights continued to be lower than controls. These

results suggest recovery from the effects of the test substance in thyroid gland, liver and ovaries, while the testes continued to be effected at the end of the study period, although some recovery was evident in the testes as well.

Microscopic evaluation revealed dose-related changes of the thyroid glands and genital systems of males and females. At week 2, follicular hyperplasia/hypertrophy of the thyroid gland with increased epithelial cell height, mitotic figures, and vesiculation of some follicular cells was noted for males and females at all dose levels, with hypertrophy being the predominant lesion and the hyperplasia being minimal. Dose-related changes in the genital system of males included decreased epididymis size, undeveloped seminal vesicles and inhibition of the process of spermatogenesis. Incomplete maturation of spermatids was observed, with the nurturing influence of the Sertoli cells no longer supporting maturation. This finding persisted in males in the high dose group at week 6, although some recovery was observed. In females at week 2, dose related vacuolation of the corpora lutea was observed. The estrous cycle of all dosed females appeared to be halted in metestrus phase, as if the normal internal cycling influences in these females were overridden. This finding was not evident at the end of the study period.

Remarks – Results

The report concluded that the dietary dosing of the analogue of the notified polymer in the feed for 14 days produced effects upon body weight, food and water consumption, hematologic and clinical chemistry parameters and microscopic changes in testes, ovaries and thyroid glands of males and females in the mid and high dose groups. At the lowest dose level, biologically significant effects were minimal in nature, and were observed only in the thyroid gland, testes and ovaries.

CONCLUSION

The No Observed (Adverse) Effect Level (NO(A)EL) for an acceptable analogue of the notified polymer was established as < 97 mg/kg bw/day in this study, based on observation of treatment-related effects at all dose levels, albeit only minimal effects were observed in the thyroid gland, testes and ovaries for the low dose level.

TEST FACILITY BRRC (1992a)

B.8. Repeat dose toxicity

TEST SUBSTANCE	Acceptable analogue of notified polymer
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METHOD

Repeated Dose Dermal Toxicity: 11-day Study.

Species/Strain

Route of Administration Dermal – occluded

Exposure Information	Total exposure days: 9 days
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Duration of exposure: 6 hours/day

Post-exposure observation period: 28 days for 10M/10F of control and high-dose group. All other animals sacrificed at Day 12.

Vehicle	Carbowax polyethylene glycol (PEG) 200
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Remarks - Method	The protocol is similar to OECD TG410 except for total exposure days (OECD TG410 has 21 days).
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RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose* mg/kg bw/day</i>	<i>Mortality</i>
control	20M/20F	0	0
low dose	10M/10F	547	0
mid dose	10M/10F	1064	0
high dose	20M/20F	1551	0

Concentrations were not adjusted for percent active ingredient of analogue chemical

Mortality and Time to Death

No mortalities were observed in any dose group throughout the study.

Clinical Observations

No treatment related clinical signs of toxicity were observed other than slight to moderate irritation of the skin that was observed in all treated animals. The irritation had completely resolved by Day 22.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

For males in the high dose group, there were increases in eosinophils, alpha 1 and 2 globulin and gamma globulin. Alpha 1 globulin was also increased in males of the mid dose group. These changes were attributed as a response to the skin irritation

Effects in Organs

No treatment related effects were observed.

Remarks – Results

No treatment related effects were observed at all dose groups other than slight to moderate skin irritation which was resolved by Day 22.

CONCLUSION

The No Observed (Adverse) Effect Level (NO(A)EL) for an acceptable analogue of the notified polymer was established as > 1551 mg/kg bw/day in this study, based on no treatment related systemic effects at all dose levels studied.

TEST FACILITY BRRC (1992b)

B.9. Repeat dose toxicity

TEST SUBSTANCE Acceptable analogue of notified polymer

METHOD Repeated Dose Inhalation Toxicity: 9-day Study.
Species/Strain Rats/Fischer-344
Route of Administration Inhalation – whole body (aerosol)
Exposure Information Total exposure days: 9 days
Duration of exposure: 6 hours/day
Post-exposure observation period: None. All animals were sacrificed at Day 9.
Vehicle None
Remarks - Method The protocol is similar to the OECD TG412 except for total exposure days (OECD TG412 has 14 or 28 days).

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose/Concentration mg/L</i>	<i>Mortality</i>
control	10M/10F	0	0
low dose	10M/10F	0.025	0
mid dose	10M/10F	0.08	0
high dose	10M/10F	0.25	1M/1F

Mortality and Time to Death

In the high dose group, one male animal died (Day 4) and one female animal was euthanised (Day 5).

Clinical Observations

Clinical signs of toxicity included rales and ocular opacities in all dose groups, yellow matting on various body surfaces and red material around the nose and mouth in the mid to high dose group and clear matting in the facial area of the low dose group.

Statistically significant mean body weight losses or reduced mean body weight gains were observed in the high dose group males during days 1 to 2 and 2 to 5. In the mid dose group, a statistically significant reduced mean body weight gain occurred in the males during days 1 to 2. Food consumption was inhibited in the mid and high dose groups males throughout the study and in the high dose group for females from days 0 to 1 through 4 to 5.

Upon microscopic examination, lesions were observed in the nasal cavities of animals in the mid and high dose groups. Exudate was present in the ventral meatus (mid dose: 2 animals and high dose: 13 animals) and necrosis was observed in the squamous epithelium (mid dose: 1 animal and high dose: 3 animals). Necrosis of the respiratory epithelium was observed in one male each in the low and mid dose groups, and 3 females in the high dose group. Lymphocytic infiltration occurred at an increased incidence in the high dose group when compared to the control and low and mid dose groups. The remaining treatment related findings in the nasal cavities were observed only in the high dose group and consisted of mucosal atrophy, erosion, suppurative inflammation, ulceration and exudate in the dorsal meatus of one to five animals.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry: Albumin levels (and corresponding A/G ratios) were significantly decreased in the high dose group for both males and females.

Haematology: In high dose group, increased mean white blood cell count in males and increased absolute numbers and percentages of segmented neutrophils for both males and females were observed.

Urinalysis: Significant increase in specific gravity and possibly reduced urine volume in high dose group were observed.

Effects in Organs

Two females in the high dose group had small thymus glands. In addition, mean absolute and relative thymus gland weights in the same group for both males and females were significantly lower than the control group values. No other treatment related effects were observed.

Remarks – Results

The notified polymer caused mortalities (high dose), clinical signs of toxicity (particularly rales, but also ocular opacities) (mid and high dose), inhibition of body weight gain and food consumption (mid and high dose), changes in clinical pathology (high dose), decreased thymus gland weights (high dose) and microscopic lesions in the nasal cavity (mid and high dose).

In the low exposure group (0.025 mg/L) there was a low incidence of ocular opacity (1 animal) and rales (2 males and 2 females one hour following exposure on study days 0, 1 or 2), and a single occurrence of mild necrosis in the nasal respiratory epithelium.

CONCLUSION

The No Observed Effect Level (NOEL) was established as < 0.025 mg/L in this study, based on a low incidence of ocular opacity and rales in the low dose group.

TEST FACILITY WIL Research Laboratories (1995b)

B.10. Genotoxicity – bacteria

TEST SUBSTANCE Notified polymer

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
 Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA
 Metabolic Activation System S9 liver microsomal fraction of Phenobarbital and β-naphthoquinone
 Concentration Range in Main Test a) With metabolic activation: 31.6-5000 µg/plate
 b) Without metabolic activation: 31.6-5000 µg/plate
 Vehicle DMSO
 Remarks - Method No significant protocol deviations. The plate incorporation method (Test 1) and pre-incubation method (Test 2) were used. The TA1535 strain was not tested in the pre-incubation method.

RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>	> 5000			
Test 1		316	> 5000	Negative
Test 2		316	> 5000	Negative
<i>Present</i>	> 5000			
Test 1		1000	> 5000	Negative
Test 2		2500	> 5000	Negative

Remarks - Results In the preliminary dose range finding study conducted on TA98 and TA100 strains only no toxicity was observed with dose levels of up to 5000 µg/plate.

Test 1: Cytotoxic effects were observed in tester strains TA1535 at doses of 2500 µg/plate and higher (without metabolic activation). In tester strain TA1537 cytotoxic effects were noted at doses of 316 µg/plate and higher (without metabolic activation) and at doses of 1000 µg/plate (with metabolic activation).

Test 2: Cytotoxic effects were observed in tester strains TA98 at doses of 1000 µg/plate and higher (without metabolic activation) and at a dose of 5000 µg/plate (with metabolic activation). In tester strain TA100 cytotoxic effects were noted at doses of 316 µg/plate and higher (without metabolic activation). In tester strain TA1535 cytotoxic effects were observed at doses of 1000 µg/plate and higher (without metabolic activation). In tester strain TA1537 cytotoxic effects were observed at doses of 316 µg/plate and higher (without metabolic activation) and at doses of 2500 µg/plate and higher (with metabolic activation).

No substantial increase in revertant colony numbers of any of the tester strains were observed following treatment with the notified polymer at any dose level, with and without metabolic activation, in either mutation test.

The concurrent positive control compounds demonstrated the sensitivity of the assay and the metabolising activity of the liver preparations.

CONCLUSION The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY BSL Services (2006e)

B.11. Genotoxicity – in vitro

TEST SUBSTANCE Acceptable analogue of notified polymer

METHOD In vitro Mammalian Chromosome Aberration Test.

Species/Strain Chinese hamster

Cell Type/Cell Line Chinese hamster ovary (CHO) cells

Metabolic Activation System S9 fraction from Aroclor 1254 induced rat liver.

Vehicle DMSO

Remarks - Method No significant protocol deviations from OECD TG 473

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL)</i>	<i>Exposure Period</i>	<i>Harvest Time</i>
<i>Absent</i>			
Test 1	0.9, 1.79, 3.57, 7.14, 11.9, 14.28	4 hr	20 hr
Test 2	0.23, 0.45, 0.90, 1.79, 3.57, 7.14	4 hr	44 hr
<i>Present</i>			
Test 1	8.5, 17.5, 35, 70, 75, 85	4 hr	20 hr
Test 2	9, 17.9, 35.7, 71.4, 142.8*	4 hr	44 hr

*Culture not selected for metaphase analysis.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>	3.57		1190	
Test 1		7.14	> 14.28	Negative
Test 2		1.79	> 7.14	Negative
<i>Present</i>	119			
Test 1		75	> 85	Negative
Test 2		71.4	> 142.8	Negative

Remarks - Results

Preliminary test

Precipitation was only observed in the preliminary test at a concentration of 1190 µg/mL. Results from the preliminary test determined the concentrations to be tested in the main test.

Main test

No precipitation was observed in the main test at any concentration studied. Excessive toxicity (i.e. complete mitotic inhibition) precluded the analysis of the 142.8 µg/mL test concentration in the S9 activated 44-hour harvest. Cytotoxicity was determined as a reduction in the mitotic index of > 50%.

The notified polymer did not induce chromosomal aberrations with and without metabolic activation at any dose level studied.

The concurrent positive control compounds demonstrated the sensitivity of the assay and the metabolising activity of the liver preparations.

CONCLUSION

The acceptable analogue of the notified polymer was not clastogenic to Chinese hamster ovary cells treated in vitro under the conditions of the test.

TEST FACILITY Microbiological Associates (1994)

B.12. Genotoxicity – in vitro

TEST SUBSTANCE Acceptable analogue of notified polymer

METHOD In vitro Mammalian Cell Gene Mutation Test.
 Species/Strain Chinese hamster
 Cell Type/Cell Line Ovary cells/CHO-K₁-BH₄
 Metabolic Activation System S9 fraction from Aroclor 1254 induced rat liver.
 Vehicle DMSO
 Remarks - Method The protocol is similar to OECD TG476

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL)</i>	<i>Exposure Period</i>	<i>Expression Time</i>	<i>Selection Time</i>
<i>Absent</i>				
Test 1	2.5, 5, 10, 20, 40	5 hr	18-24 hr	7-9 days
Test 2	5, 10, 20, 30, 40	5 hr	18-24 hr	7-9 days
<i>Present</i>				
Test 1	12.5, 25, 50, 75, 125	5 hr	18-24 hr	7-9 days
Test 2	50, 60, 70, 85, 100	5 hr	18-24 hr	7-9 days

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>	50			
Test 1		40	> 5000	Negative
Test 2		40	> 5000	Negative
<i>Present</i>	150			
Test 1		125	> 5000	Negative
Test 2		100	> 5000	Negative

Remarks - Results

CONCLUSION The acceptable analogue of the notified polymer not clastogenic to Chinese hamster cells treated in vitro under the conditions of the test.

TEST FACILITY Microbiological associates (1994)

B.13. Genotoxicity – in vivo

TEST SUBSTANCE Acceptable analogue of notified polymer

METHOD Mammalian Erythrocyte Micronucleus Test.
 Species/Strain Mice/Sprague Dawley
 Route of Administration Intraperitoneal injection
 Vehicle Distilled water
 Remarks - Method Method similar to OECD TG 474 Mammalian Erythrocyte Micronucleus Test. Bone marrow cells collected and analysed for micronucleated polychromatic chromosomes at 24, 48 and 72 hours

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Sacrifice Time hours</i>
I (vehicle control)	5M/5F	0	24, 48 and 72 hrs
II (low dose)	5M/5F	40	24, 48 and 72 hrs
III (mid dose)	5M/5F	80	24, 48 and 72 hrs
IV (high dose)	5M/5F	160	24, 48 and 72 hrs
V (positive control, cyclophosphamide)	5M/5F	40	24 hrs

RESULTS

Doses Producing Toxicity

Mortality occurred within one hour of dose administration as follows: 3/5 males and 5/5 females treated with 250 mg/kg and 5/5 males and 5/5 females treated with 500, 1000 and 2000 mg/kg.

Genotoxic Effects

No significant increase in the number of micronucleated polychromatic erythrocytes was observed.

Remarks - Results

Positive control group showed a marked increase in the incidence of micronucleated polychromatic erythrocytes, demonstrating the sensitivity of the test.

CONCLUSION

The acceptable analogue of the notified polymer was not clastogenic under the conditions of this in vivo mouse micronucleus test.

TEST FACILITY

Microbiological associates (1994)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer (> 70%)
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Activated sludge from domestic sewage treatment plant, Rossdorf, Germany
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Manometry (change of pressure in test flasks due to oxygen consumption).
Remarks - Method	Oxygen demand of inoculum control and pH values of test flasks met validity criteria.

RESULTS

<i>Test substance</i>		<i>Sodium benzoate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
4	0	4	64
28	2	16	100

Remarks - Results The ready biodegradability of the reference substance sodium benzoate was confirmed under the culture conditions used for the test. There was no microbial inhibition in the toxicity control (test and reference substances combined).

CONCLUSION The notified polymer is not readily biodegradable.

TEST FACILITY IBACON (2006)

C.1.2. Bioaccumulation

No bioaccumulation test was provided. The notified polymer is poorly degradable and has a log Pow of 4.9, but is not expected to bioaccumulate because of its molecular weight and surface activity.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer (> 70%)
METHOD	OECD TG 203 Fish, Acute Toxicity Test - static.
Species	Rainbow trout (<i>Oncorhynchus mykiss</i>)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg CaCO ₃ /L
Analytical Monitoring	DOC measurement after filtration (0.2 micron).
Remarks – Method	Test media were slightly aerated during the test. Measured concentrations were 91% of nominal at the start of the test and 100% in the aged test media.

RESULTS

Nominal Concentration mg/L	Number of Fish	Mortality				
		1 h	24 h	48 h	72 h	96 h
0	7	0	0	0	0	0
0.43	7	0	0	0	2	2
0.94	7	0	0	0	0	0
2.1	7	0	0	0	0	0
4.6	7	0	7			
10	7	0	7			

LC50 2.94 mg/L at 96 hours.

NOEC 0.43 mg/L at 96 hours.

Remarks – Results Test media remained clear throughout the exposure period. All fish were killed within 2 hours at 10 mg/L, after showing signs of intoxication (strong ventilation and strongly extended gills). The mortalities observed at the lowest test concentration reflect territorial aggression by one fish, rather than intoxication by the test substance.

CONCLUSION The notified polymer is toxic to fish.

TEST FACILITY IBACON (2007a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer (> 70%)

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - static.

Species *Daphnia magna*

Exposure Period 48 hours

Auxiliary Solvent None

Water Hardness 250 mg CaCO₃/L

Analytical Monitoring DOC measurement after filtration (0.2 micron).

Remarks - Method Test media were prepared immediately before testing. Measured concentrations were 93% of nominal at the start of the test and 115% in the aged test media.

RESULTS

Nominal Concentration mg/L	Number of <i>D. magna</i>	Number Immobilised	
		24 h	48 h
0	20	0	0
0.43	20	0	0
0.94	20	0	0
2.1	20	0	0
4.6	20	0	7
10	20	18	20

EC50 7.1 mg/L at 24 hours

4.8 mg/L at 48 hours

NOEC 4.5 mg/L at 24 hours

2.1 mg/L at 48 hours

Remarks – Results Test media remained clear throughout the exposure period.

CONCLUSION The notified polymer is toxic to daphnids.

TEST FACILITY IBACON (2007b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer (> 70%)
METHOD	OECD TG 201 Alga Growth Inhibition Test.
Species	<i>Desmodesmus subspicatus</i>
Exposure Period	72 hours
Concentration Range	Nominal: 0.0093-10 mg/L (confirmed by analysis)
Auxiliary Solvent	None
Water Hardness	24 mg CaCO ₃ /L
Analytical Monitoring	DOC measurement after filtration (0.2 micron).
Remarks - Method	Test media were prepared immediately before introduction of the algae
RESULTS	The 72 hour EC50s were 6.79 mg/L based on growth rate, 1.87 mg/L based on biomass, and 1.31 mg/L based on yield.
Remarks – Results	Test media remained clear throughout the exposure period. The cell density in controls increased 164 fold within 72 hours, satisfying the validity criterion. Microscopic examination of the algae after 72 hours at the highest exposure found no difference in shape compared with controls.
CONCLUSION	The notified polymer is toxic to green algae.
TEST FACILITY	IBACON (2007c)

BIBLIOGRAPHY

- BRRC (1992a) *Analogue chemical*: Fourteen-day dietary study in Fischer 344 rats (Project ID 93U1237, 29 June 1994). Bushy run research center, Union Carbide Chemicals and Plastics Company Inc., Export, Pennsylvania, USA. (Unpublished report provided by notifier).
- BRRC (1992b) *Analogue chemical*: Nine-day repeated dose toxicity cutaneous dose toxicity study in Fischer 344 rats (Project ID 91O0011, 5 November 1992). Bushy run research center, Union Carbide Chemicals and Plastics Company Inc., Export, Pennsylvania, USA. (Unpublished report provided by notifier).
- BSL Bioservice (2006a) Acute oral toxicity – Acute toxic class method with Y-17112 (Project No. 061786, 18 September 2006). BSL Bioservice Scientific Laboratories GmbH, Planegg, Germany. (Unpublished report provided by notifier).
- BSL Bioservice (2006b) Acute dermal toxicity (Limit test) with Y-17112 (Project No. 061787, 31 August 2006). BSL Bioservice Scientific Laboratories GmbH, Planegg, Germany. (Unpublished report provided by notifier).
- BSL Bioservice (2006c) Acute dermal irritation/corrosion with Y-17112 (Project No. 061788, 31 August 2006). BSL Bioservice Scientific Laboratories GmbH, Planegg, Germany. (Unpublished report provided by notifier).
- BSL Bioservice (2006d) Acute eye irritation/corrosion with Y-17112 (Project No. 061789, 28 September 2006). BSL Bioservice Scientific Laboratories GmbH, Planegg, Germany. (Unpublished report provided by notifier).
- BSL Bioservice (2007) Test for sensitization (Guinea pig maximization test) with Y-17112 (Project No. 061790, 18 January 2007). BSL Bioservice Scientific Laboratories GmbH, Planegg, Germany. (Unpublished report provided by notifier).
- BSL Bioservice (2006e) Reverse mutation assay using bacteria (*Salmonella typhimurium* and *Escherichia coli*) with Y-17112 (Project No. 061791, 18 August 2006). BSL Bioservice Scientific Laboratories GmbH, Planegg, Germany. (Unpublished report provided by notifier).
- FORS (Federal Office of Road Safety) (1998) Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 6th Edition, Canberra, Australian Government Publishing Service
- HERA (2005) Guidance Document: Methodology. Human & Environmental Risk Assessment on Ingredients of Household Cleaning Products; February 2005
- IBACON (2006) Ready biodegradability of Y-17112 in a manometric respirometry test (IBACON study 31124163, 7 September 2006). Rossdorf, Germany (Unpublished report provided by notifier).
- IBACON (2007a) Acute toxicity of Y-17112 to rainbow trout (*Oncorhynchus mykiss*) in a 96-hour static test (IBACON study 31123230, 28 March 2007). Rossdorf, Germany (Unpublished report provided by notifier).
- IBACON (2007b) Acute toxicity of Y-17112 to *Daphnia magna* in a static 48-hour immobilisation test (IBACON study 31122220, 23 March 2007). Rossdorf, Germany (Unpublished report provided by notifier).
- IBACON (2007c) Toxicity of Y-17112 to *Desmodesmus subspicatus* in an algal growth inhibition test (IBACON study 31121210, 26 February 2007). Rossdorf, Germany (Unpublished report provided by notifier).
- Microbiological Associates (1994) [Analogue]: In vitro mammalian cytogenetic test (Study No. G94AT04.332, 12 December 1994). Microbiological associates, Inc., Rockville, Maryland, USA.
- Microbiological Associates (1994) [Analogue]: Micronucleus cytogenic assay in mice (Study No. G94AT04.122, 11 November 1994). Microbiological associates, Inc., Rockville, Maryland, USA.
- Microbiological Associates (1994) [Analogue]: CHO/HGPRT mutation assay with confirmation (Study No. G94AT04.782001, 14 December 1994). Microbiological associates, Inc., Rockville, Maryland, USA.
- Momentive Performance (2008a) Analysis of water extractability of Y-17112 Lot K36A061207 by HPLC. Momentive Performance Materials, Research and Development, Silicones Building, Tarrytown, USA. (Unpublished report provided by notifier).

- Momentive Performance (2008b) Analysis of octanol/water partition coefficient of Y-17112 Lot K36A061207 by HPLC. Momentive Performance Materials, Research and Development, Silicones Building, Tarrytown, USA. (Unpublished report provided by notifier).
- NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- SDA (2005) Exposure and Risk Screening Methods for Consumer Products Ingredients. Washington, The Soap and Detergent Association
- TASQA (1994) [Analogue]: Determinacao da taxa de hidrolise em funcao do pH. TASQA study TSQ-P399/93 dated 29 March 1994, Paulinia, Brazil. (Unpublished report provided by notifier).
- United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.
- WIL Research Laboratories (1995a) An acute inhalation toxicity study of *analogue chemical* in Albino Rats (Project No. WIL-242003, September 1995). WIL Research Laboratories, Ashland, Ohio, USA. (Unpublished report provided by notifier).
- WIL Research Laboratories (1995b) A 9-day inhalation toxicity study of *analogue chemical* in rats (Project No. WIL-242004, 3 October 1995). WIL Research Laboratories, Ashland, Ohio, USA. (Unpublished report provided by notifier).