

File No: LTD/1540

August 2012

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

PUBLIC REPORT

PVOH Polymer

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

**Director
NICNAS**

TABLE OF CONTENTS

SUMMARY	3
CONCLUSIONS AND REGULATORY OBLIGATIONS	3
ASSESSMENT DETAILS	5
1. APPLICANT AND NOTIFICATION DETAILS	5
2. IDENTITY OF CHEMICAL.....	5
3. COMPOSITION.....	5
4. PHYSICAL AND CHEMICAL PROPERTIES	5
5. INTRODUCTION AND USE INFORMATION	6
6. HUMAN HEALTH IMPLICATIONS	7
7. ENVIRONMENTAL IMPLICATIONS.....	7
<u>APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES</u>	<u>11</u>
<u>APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS</u>	<u>12</u>
BIBLIOGRAPHY	19

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1540	Procter & Gamble Australia Pty Ltd Costco Wholesale Australia Pty. Ltd.	PVOH Polymer	ND*	≤ 14 tonnes per annum	A component of dishwashing tablets

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment

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

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

Environmental risk assessment

On the basis of the PEC/PNEC ratio and assessed use pattern the notified polymer is not expected to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

CONTROL MEASURES

Occupational Health and Safety

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

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

Secondary Notification

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

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

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of dishwashing tablets, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 14 tonnes per annum, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

Material Safety Data Sheet

The MSDS of 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.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Procter & Gamble Australia Pty Ltd (ABN 91 008 396 245)
Level 4, 1 Innovation Road
MACQUARIE PARK, NSW 2113

Costco Wholesale Australia Pty Ltd (ABN 57 104 012 893)
82 Waterloo Road
MACQUARIE PARK, NSW 2113

NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn \geq 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physico-chemical properties, except for water solubility.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA, China and Canada.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

PVOH Polymer

MOLECULAR WEIGHT

> 10,000 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS Below classification cut-offs.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Not expected to occur under normal conditions of use.

DEGRADATION PRODUCTS

Not expected to occur under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Clear colourless liquid, however the imported finished product containing the notified polymer is a solid.

Property	Value	Data Source/Justification
----------	-------	---------------------------

Melting Point/Freezing Point	< 20°C	Estimated based on the state of the notified polymer at room temperature.
Boiling Point	Not determined	The notified polymer would be expected to decompose prior to boiling
Density	Not determined	Introduced as part of a solid mixture
Vapour Pressure	< 1.3×10^{-9} kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2007)
Water Solubility	~327 g/L at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	Contains functionality that may slowly hydrolyse in the environmental pH range (4-9)
Partition Coefficient (n-octanol/water)	Not determined	Expected to have a low partition coefficient on the basis of its high water solubility
Adsorption/Desorption	Not determined	Expected to have low mobility in soil based on its high molecular weight
Dissociation Constant	Not determined	The notified polymer is a salt and is expected to be ionised under environmental conditions
Particle Size	Not determined	Introduced in film form.
Flash Point	Not determined	Expected to be high based on the very low predicted vapour pressure.
Flammability	Not determined	Not expected to be highly flammable.
Autoignition Temperature	Not determined	Expected to decompose prior to ignition.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosives.
Oxidising Properties	Not expected to be oxidising	Estimated based on chemical structure.

DISCUSSION OF PROPERTIES

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

Reactivity

Stable under normal conditions of use.

Dangerous Goods classification

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

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as a component of a finished dishwashing product.

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

Year	1	2	3	4	5
Tonnes	10-14	8-12	8-12	8-12	8-12

PORT OF ENTRY

Port Botany

TRANSPORTATION AND PACKAGING

Dishwashing tablets wrapped in packaging incorporating the notified polymer will be imported as finished consumer products that will be transported by road (primarily) and rail within Australia.

USE

The notified polymer will be used as a component of soluble packaging for dishwashing tablets. The notified polymer will be 3 – 5% of the total weight of the dishwashing tablet. The notified polymer does not contribute to the cleaning properties of the dishwashing tablet.

OPERATION DESCRIPTION

The notified polymer will not be manufactured, reformulated or repackaged within Australia.

The imported dishwasher tablets will be transported from the port to the notifiers' warehouses prior to being sent to retail stores for sale to the public.

During end use the public will remove a dishwashing tablet from the box containing them and place it into the detergent reservoir in the dishwasher. The film packaging containing the notified polymer that covers the dishwashing tablet will not be removed but will dissolve in the dishwasher releasing the contents. The notified polymer will be discharged into the wastewater at the end of the dishwashing cycle.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

It is anticipated that workers would only be exposed to the notified polymer in the event of accidental spillage during transport and storage. Exposure would be limited to dermal contact and is expected to be limited by the notified polymer being contained within the film packaging.

6.1.2. Public Exposure

The public will be dermally exposed to the notified polymer during transfer of the dishwasher tablets to dishwashing machines. Dermal contact with the packaging will be brief with exposure expected to be less than 1 minute per day and only to the fingertips. The notified polymer is bound in the film packaging and transfer to the skin during dermal exposure is expected to be low.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

The notified polymer is not expected to be absorbed across the gastrointestinal tract or the skin based on the high molecular weight (> 10,000 Da.) and the absence of low molecular weight (< 1,000 Da.) species. Furthermore, the notified polymer does not contain any structural alerts of concern and is therefore expected to be of low hazard to human health.

Health hazard classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

As worker exposure to the notified polymer will be limited to spills due to an accident, and considering the expected low hazardous nature of the notified polymer, the risk to these workers is not considered to be unreasonable.

6.3.2. Public Health

The public will experience dermal exposure to film packaging containing the notified polymer. However, exposure is expected to be low as the notified polymer will be bound within the film packaging and combined with the expected low hazard the risk to the public from the notified polymer is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured, reformulated or repackaged in Australia; therefore there will be no release from these activities. Environmental release during importation, transport, storage and distribution may occur as a result of accidental spills. Spills are expected to be contained, collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified polymer is expected to be released to sewers nationwide in wastewater from dishwashers following use.

RELEASE OF CHEMICAL FROM DISPOSAL

Some of the notified polymer may be disposed of to landfill in domestic waste when unused dishwashing tablets are discarded.

7.1.2. Environmental Fate

The notified polymer is expected to be hydrolytically stable under environmental conditions based on structural considerations. The notified polymer is not readily biodegradable but is considered to be inherently biodegradable on the basis of the provided studies (for study details, refer to Appendix B).

The majority of the notified polymer is expected to be released to sewage treatment plants (STPs) in domestic wastewater. Based on its molecular weight and high water solubility, up to 75% removal of the notified polymer from STP effluent is anticipated via adsorption to sludge (US EPA, 2007). Notified polymer in treated sewage effluent may be released to surface waters or applied to land when used for irrigation. Notified polymer in sewage sludge may be disposed of to landfill or applied to land when sludge is used for soil remediation. Notified polymer reaching surface waters or in soils is not expected to be bioaccumulative due to its high water solubility. Despite its high water solubility, notified polymer applied to soils or in landfill is expected to have low mobility due to its high molecular weight.

The notified polymer is likely to degrade and form low molecular weight (<1000 Da) metabolites in STPs, surface waters, soils and landfill due to its inherent biodegradability. Based on the modelled data for two representative oligomers with a molecular weight of approximately 300 Da, low molecular weight metabolites of the notified polymer are: predicted to be highly water soluble (>50 g/L, WSKOW, v1.42; US EPA, 2011); unlikely to bioaccumulate based on the predicted partition coefficient (log Kow <0.2, KOWWIN, v1.68; US EPA, 2011); and, expected to have low sorption to soils based on the predicted high water solubility. The low molecular weight metabolites are expected to further degrade in both the aquatic and terrestrial compartments through biotic and abiotic processes to form water, oxides of carbon and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)

Under a worst case scenario, assuming all of the annual import volume of notified polymer is released to sewers over 365 days with no removal of the notified polymer in the sewage treatment plant (STP), the Predicted Environmental Concentration (PEC) for release of sewage effluent on a nationwide basis would be 8.48 µg/L in rivers and 0.85 µg/L in oceans.

However, a more realistic exposure scenario includes 75% removal of the notified polymer by adsorption to sludge during STP processes. Therefore, the resultant PEC in sewage effluent on a nationwide basis are estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	14,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	14,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	38.36	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million

Removal within STP	75%
Daily effluent production:	4,523 ML
Dilution Factor - River	1
Dilution Factor - Ocean	10
PEC - River:	2.12 µg/L
PEC□ - Ocean:	0.21 µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 63.608 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m³ and a soil-mixing zone of 10 cm, the concentration of the notified polymer may approximate 0.424 mg/kg in applied soil. This assumes that degradation of the notified polymer occurs in the soil within 1 year from application. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated biosolids application, the concentration of notified polymer in the applied soil in 5 and 10 years may approximate 2.12 mg/kg and 4.24 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 2.12 µg/L may potentially result in a soil concentration of approximately 0.014 mg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 0.071 mg/kg and 0.141 mg/kg, respectively.

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 B.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	96 h LC50 = 470 mg/L	Not harmful to fish
Daphnia Toxicity	48 h LC50 = 250 mg/L	Not harmful to aquatic invertebrates

The available measured results were indicative of low hazard to fish and aquatic invertebrates. However, the notified polymer is an anionic polymer. Anionic polymers are generally of low toxicity to fish and aquatic invertebrates but are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone, which is unlikely to apply to the notified polymer due to the addition of non-chelating functionality. Further, the indirect toxicity to algae is likely to be mitigated due to the presence of calcium ions in the aquatic compartment, which can bind to the functional groups of the notified polymer.

Based on the available measured acute toxicity endpoints, the notified polymer is not harmful to fish and aquatic invertebrates. Therefore, the notified polymer is not formally classified for acute aquatic hazard under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009). The notified polymer is not rapidly degradable and is not considered to have potential for bioaccumulation. On the basis of its acute toxicity, the notified polymer is not classified for long-term aquatic hazard under the GHS.

Based on the modelled data for two representative oligomers with a molecular weight of approximately 300 Da, the low molecular weight metabolites of the notified polymer are predicted have acute toxicity endpoints that are much greater than 100 mg/L for all three trophic levels. Therefore, the low molecular weight metabolites are expected to be of low hazard to aquatic organisms.

7.2.1. Predicted No-Effect Concentration

The Predicted No Effect Concentration (PNEC) has been calculated from the daphnid acute toxicity and an assessment factor of 1000. A conservative assessment factor of 1000 was used as acute toxicity endpoints are available for aquatic species from two trophic levels. However, the available measured endpoints were not considered to represent the most sensitive species.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment	
LC50 (Invertebrates)	250 mg/L
Assessment Factor	1,000

PNEC:

250 µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotients (Q) have been calculated for the aquatic compartment:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	2.12	250	0.008
Q - Ocean	0.21	250	0.0□1

The risk quotient for discharge of treated effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on its annual introduction volume and the partial removal from waste water by sorption to sewage sludge. The notified polymer is inherently biodegradable. It is thus unlikely to persist in surface waters or soils and is expected to degrade to form low molecular weight metabolites. Both the notified polymer and its low molecular weight metabolites are considered to have low potential for bioaccumulation and are expected to be of low hazard to aquatic organisms. Therefore, on the basis of the PEC/PNEC ratio and assessed use pattern the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Water Solubility**

~327 g/L at 20 °C

Method	In house.
Remarks	Measured amounts of the test substance (up to 99.9 g) were added to 300 mL of water, at ambient temperature (20±1 °C) and under constant agitation, until the solubility endpoint was reached. The endpoint was defined as when the viscosity of the solution increased to the point where further agitation did not adequately mix the solution. This was evidenced by small portions of film observed near the top of the mixture. After several hours of mixing the solution became opaque, although it is unclear if this was due to incorporation of air bubbles or film dissolution. The solubility was found to be approximately 327 mg/mL in water under the conditions of the test.
Test Facility	MonoSol, LLC (2011)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Environmental Fate

B.1.1. Ready biodegradability

TEST SUBSTANCE	Three water-soluble films containing the notified polymer (Film 1 contains the notified polymer at ~60%; the percentage composition of notified polymer in the other two films was not reported)
METHOD	OECD TG 301 B Ready Biodegradability: CO ₂ Evolution Test. EC Directive 67/548/EEC C.4-C Carbon dioxide (CO ₂) Evolution.
Inoculum	Activated sludge (domestic, ≤ 30 mg/L), pre-adapted (semi-continuous activated sludge unit dosed with the test substance at a nominal concentration of 20 mg C/L for ~40 days: see C.1.3.)
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	TOC
Remarks - Method	The test was conducted according to the guidelines above and in compliance with the principles of good laboratory practice. The blank control, reference (sodium benzoate, ~10 mg C/L) and test substance (~10 mg C/L) treatments were performed in duplicate. Toxicity controls were dosed with both the reference compound (~10 mgC/L) and test substance (~10 mg C/L). The CO ₂ trap (KOH solution) nearest the test solutions were removed for IC analysis on days 3, 6, 10, 13, 17, 21, 24 and 27: the two remaining traps were moved one position closer to the test chamber and a new trap was placed at the end of the series. Dissolved organic carbon concentrations of the test samples were determined on Day 0 and Day 29. Test conditions: 22 ± 2°C, pH 7.3-7.4. Biodegradability was calculated by determining the amount of CO ₂ produced from the test substance, corrected by an inoculum blank, and the theoretical amount of CO ₂ (ThCO ₂) that could have been produced if complete biodegradation of the test substances had occurred.

RESULTS

<i>Day (Test substance)</i>	<i>% Degradation by ThCO₂ (Standard deviation)</i>		
	<i>Film 1</i>	<i>Film 2</i>	<i>Film 3</i>
3	6.4 ^a	3.9 ^a	5.2 ^a
6	14.1 ^a	9.6 ^a	10.5 ^a
10	21.3 ^a	19.3 ^a	15.4 ^a
13	24.2 ^a	24.8 ^a	17.8 ^a
17	29.3 ^a	32.9 ^a	21.6 ^a
21	33.9 ^a	40.4 ^a	25.5 ^a
24	37.7 ^a	46.0 ^a	28.4 ^a
27	40.8 ^a	53.6 ^a	30.7 ^a
29	44.4 ^a (3.6)	60.1 ^a (8.6)	32.9 ^a (7.7)
<i>Toxicity Control at day 13</i>	56.7	60.0	52.8

^a Average of two replicates

Remarks - Results

The following deviations were reported to the protocol: characterisation and stability of the test and reference substance were not conducted; on one day the measured temperature range fell outside the stated range (19 °C to 20 °C). The deviations were not considered to impact the integrity of the study. However, contrary to the OCED protocol the inoculum was pre-adapted to the test substance. Therefore, the results should be treated with caution.

The reference substance control reached the pass levels by Day 14 (69.0% on Day 6). The total amount of CO₂ evolved from the controls did not exceed 40 mg/L. The toxicity test for each of the three test substances showed biodegradation in excess of 25%; therefore, the test substances were not assumed inhibitory at the test concentration. The differences in replicate values were less than 20%. Therefore, the validity criteria of the test were met.

The three test substances did not meet the pass level of 60% (based on ThCO₂) within 10 days of reaching 10% degradation. None of the three test substances reached the pass level by Day 28, and only one of the three test substances reached the pass level by Day 29. Biodegradation ranged 32.9% to 60.1% at Day 29 for the three test substances. Therefore, the test substances were not readily biodegradable under the conditions of the test.

CONCLUSION Three water-soluble films containing the notified polymer were not readily biodegradable

TEST FACILITY Wildlife International, Ltd. (2003a)

B.1.2. Ready biodegradability

TEST SUBSTANCE Notified polymer (purified from a water-soluble film containing the notified polymer at ~60%; the film was extracted with methanol and filtered over a 10,000 molecular weight cut-off membrane)

METHOD OECD TG 301 B Ready Biodegradability: CO₂ Evolution Test.
EC Directive 67/548/EEC C.4-C Carbon dioxide (CO₂) Evolution.

Inoculum Activated sludge (domestic, ≤ 30 mg/L), pre-adapted (semi-continuous activated sludge unit dosed with the test substance at a nominal concentration of 20 mg C/L for ~40 days: see C.1.3.)

Exposure Period 28 days

Auxiliary Solvent None

Analytical Monitoring TOC

Remarks - Method The test was conducted according to the guidelines above and in compliance with the principles of good laboratory practice. The blank control, reference (sodium benzoate, ~10 mg C/L) and test substance (~10 mg C/L) treatment were performed in duplicate. The toxicity control was dosed with both the reference compound (~10 mgC/L) and test substance (~10 mg C/L). The CO₂ trap (KOH solution) nearest the test solutions were removed for IC analysis on days 1, 4, 6, 8, 11, 15, 18, 21, 26, 29, 32, 35 and 39: the two remaining traps were moved one position closer to the test chamber and a new trap was placed at the end of the series. Dissolved organic carbon concentrations of the test samples were determined on Day 0 and Day 40. Test conditions: 22 ± 2°C, pH 7.4.

Biodegradability was calculated by determining the amount of CO₂ produced from the test substance, corrected by an inoculum blank, and the theoretical amount of CO₂ (ThCO₂) that could have been produced if complete biodegradation of the test substances had occurred.

RESULTS

Day	% Degradation by ThCO ₂ (Standard deviation)		
	Test substance	Reference substance	Toxicity control
1	0.4 ^a		
4	4.2 ^a		26.1
6	8.6 ^a	62.3 ^a	
8	17.1 ^a		
11	28.7 ^a		
15	40.5 ^a	89.5 ^a	57.6
18	46.0 ^a		
21	50.4 ^a		
26	58.5 ^a		
29	60.7 ^a		
32	62.8 ^a		
35	64.5 ^a		
39	65.1 ^a (1.2)		

^a Average of two replicates

Remarks - Results

The following deviations were reported to the protocol: characterisation and stability of the test and reference substance were not conducted. The deviations were not considered to impact the integrity of the study. However, contrary to the OCED protocol the inoculum was pre-adapted to the test substance. Therefore, the results should be treated with caution.

The reference substance control reached the pass levels by Day 14 (62.3% on Day 6). The total amount of CO₂ evolved from the controls did not exceed 40 mg/L. The toxicity test showed biodegradation in excess of 25%; therefore, the test substance was not assumed inhibitory at the tested concentration. The differences in replicate values were less than 20%. Therefore, the validity criteria of the test were met.

The test substances did not meet the pass level of 60% (based on ThCO₂) within 10 days of reaching 10% degradation (Day 8 - 17.1%; Day 18 - 46.0%). The test substance did not reach the pass level of 60% ThCO₂ by Day 28. Biodegradation was 60.7% at Day 29 and 65.1% at Day 39. Therefore, the test substance was not readily biodegradable under the conditions of the test.

CONCLUSION

The notified polymer is not readily biodegradable

TEST FACILITY

Wildlife International, Ltd. (2003b)

B.1.3. Inherent biodegradability

TEST SUBSTANCE

Notified polymer (purified from a water-soluble film containing the notified polymer at ~60%; the film was extracted with methanol and filtered over a 10,000 molecular weight cut-off membrane.)

METHOD

OECD TG 302 A Inherent Biodegradability: Modified SCAS Test.
OPPTS 835.3210 Modified SCAS Test.

Inoculum

Activated sludge (preconditioned, domestic, 1667 mg total suspended solids/L)

Exposure Period

41 days

Auxiliary Solvent

None

Analytical Monitoring

DOC

Remarks – Method

The study was conducted in accordance with the guideline above and in compliance with the principles of good laboratory practice. Control and treatment (test substance at 20 mg C/L) groups were preformed in

duplicate at 20 °C to 22 °C. The test vessels are spiked with the required amount of test substance to give a nominal 20 mg C/L and brought to volume (1.5 L) with domestic sewage each day prior to aeration. Following the aeration period of 23.5 h, the air flow was stopped and the sludge was allowed to settle for 30 minutes and 1 L of effluent was removed from each vessel. The cycle is repeated daily. DOC analysis was performed on the drained effluent three times weekly over the 41-day test period.

RESULTS

<i>Average DOC Removal</i>			
<i>Days 1 to 29</i>	<i>Days 22 to 29</i>	<i>Days 31 to 41</i>	<i>Entire test</i>
37%	55.9%	78.9%	48.7%

Remarks – Results

The following deviations to the study protocol were reported: 10 mL of synthetic sewage were added to the test vessels on Days 0 to 9; domestic sewage was not stirred while being stored in the refrigerator. The deviations were not considered to impact the integrity of the study.

Carbon removal for the test substance treatment ranged from 6.0 to 90.5% with an average removal of 48.7% during the 41-day test. The test substance may be considered inherently biodegradable since greater than 20% removal was observed under the conditions of the test.

CONCLUSION

The notified polymer may be considered inherently biodegradable

TEST FACILITY

Wildlife International, Ltd. (2002)

B.1.4. Aerobic biodegradation under controlled composting conditions

TEST SUBSTANCE

Notified polymer (cellulose powder used as reference item)

METHOD

ASTM D 5338, Standard Test Method for Determining Aerobic Biodegradation in Soil of Plastic Materials under Controlled Composting Conditions.

Duration

45 days

Incubation temperature

Day 0-1 35 °C

Day 1-5 58 °C

Day 5-38 50 °C

Day 28-45 35 °C

Remarks – Method

The test substance and reference item were each mixed with inoculum in approximate ratios of 1-1.5 parts test substance dry matter to 6 parts inoculum total solids. The mixtures were incubated in airtight reactors (one replicate each), with shaking at weekly intervals. The inoculum was derived from the organic fraction of municipal solid waste, by stabilisation and maturation in a compost bin over three months under controlled aeration, followed by sieving (5 mm screen).

The incubated mixtures were aerated by pressurised dry air, with precise control of flow rates. Analysis of exhaust gases for CO₂ at regular intervals (3.5 hours) together with measurement of flow rate, allowed the percentage conversion of C to CO₂ to be determined, after subtraction of background production from the blank inoculum.

RESULTS

Biodegradation of cellulose was rapid, reaching a biodegradation percentage of 70% after 28 days. The rate of CO₂ evolution slowed after this with carbon conversion reaching 75% after 45 days.

The compost samples containing the test substance maintained a loose, crumbly structure for the duration of the test. The sample remained visible and no fungi were observed. At the end of the test the dry matter was 55.4% with a pH of 8.6.

CO₂ evolution from samples of the test substance started slowly and levelled off after 30 days. Mineralisation for the test substance was 10.6% with a standard deviation of 0.8% and 95% confidence interval of $\pm 1.3\%$. The test substance degraded 14.2% with respect to cellulose.

CONCLUSION Very slowly biodegradable in compost

TEST FACILITY OWS Inc (1993)

B.2. Ecotoxicological Investigations

B.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified polymer (100%)

METHOD Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. U.S. Environmental Protection Agency, Ecological Research Series EPA-660/3-75-009, 1975.

Similar to OECD TG 203 Fish, Acute Toxicity Test – Static.
Bluegill sunfish (*Lepomis macrochirus*, 0.63 ± 0.18 g, 29 ± 2.2 mm)

Species
Exposure Period 96 hour

Auxiliary Solvent None

Water Hardness 46-48 mg CaCO₃/L

Analytical Monitoring None

Remarks – Method After a range finding test, a definitive test in accordance with the guideline above and in compliance with GLP standards and principles.

A blank control was run in conjunction with 6 test concentrations in a geometric series with a factor of 1.8. Ten fish were exposed at each treatment level and control under static conditions. The test substance was added to the test solutions via direct weighing of the film at concentrations ranging 56 mg/L and 1000 mg/L in reconstituted dilution water. Results are based on nominal concentrations (not corrected for purity). Test conditions were: 20-21 °C; pH 6.5-7.7; 0.4-9.3 mg O₂/L; 16 h light/8 h dark.

Non-linear interpolation and binominal method were used for the statistical analysis of the data and the determination of the 95% confidence interval (where the dose response occurred over a reasonable range).

RESULTS

Nominal Concentration (mg/L)	Number of Fish	% Mortality			
		24 h	48 h	72 h	96 h
Control	10	0	0	0	0
56	10	0	0	0	0
100	10	0	0	0	0
180	10	0	0	0	0
320	10	0	0	0	0
560	10	0	0	80	80
1000	10	0	80	100	100

LC50 (95% confidence limits) > 1000 mg/L at 24 hours.
830 mg/L at 48 hours.

NOEC
Remarks – Results

470 (320-1000) mg/L at 72 hours.
470 (320-1000) mg/L at 96 hours.
320 mg/L at 96 hours.
There was no mortality in the control.

The dissolved oxygen concentration remained above 60% saturation in the control but fell below 60% saturation in all treatments at 48 hours. Decreasing dissolved oxygen concentration was observed with increasing test substance concentration. For the 560 mg/L and 1000 mg/L test solutions the dissolved oxygen saturation decreased to lows of 9.2% and 4.6% respectively at 72 hours. Low dissolved oxygen concentrations may give rise to endpoints that either over- or under-estimate the toxicity of the test substance. Therefore, the OECD validity criteria for the test are not met and the results should be treated with caution.

As small amount of foam was observed on the surface of all test solutions; this dissipated within half an hour with stirring of the 56 and 100 mg/L test solutions, and from the remainder of the test solutions after 72 hours.

The 96-hour median lethal dose was determined to be 470 mg/L with a 95% confidence interval of 320 mg/L to 1000 mg/L. Mortality, surfacing and laboured respiration were observed in the 560 and 1000 mg/L test solutions. Effects were not observed at test concentrations below 560 mg/L. Therefore, the no-observed-effect concentration was 320 mg/L.

CONCLUSION

The notified polymer is not harmful to fish

TEST FACILITY

Analytical Biochemistry Laboratories Inc (1986a)

B.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE

Notified polymer (100%)

METHOD

Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. U.S. Environmental Protection Agency, Ecological Research Series EPA-660/3-75-009, 1975.

Similar to OECD TG 202 *Daphnia* sp. Acute Immobilisation Test - Static. *Daphnia magna* (< 24-hour old, first instar)

Species

Exposure Period

48 hours

Auxiliary Solvent

None

Water Hardness

225-275 mg CaCO₃/L

Analytical Monitoring

None

Remarks - Method

After a range finding test, a definitive test in accordance with the guideline above and in compliance with GLP standards and principles. There were no significant deviations to the protocol.

A blank control was run in conjunction with 5 test concentrations in a geometric series with a factor of 1.8. 15 daphnia were exposed at each treatment level and control (3 replicates of 5 daphnia each) under static conditions. The test substance was added to the test solutions via direct weighing of the film (not corrected for purity) at concentrations ranging 56 mg/L and 1000 mg/L in natural well dilution water. Results are based on nominal concentrations (not corrected for purity). Test conditions were: 21-23 °C; pH 8.0-8.3; 8.1-8.6 mg O₂/L; 16 h light/8 h dark.

Non-linear interpolation and binominal method were used for the statistical analysis of the data and the determination of the 95% confidence interval (where the dose response occurred over a reasonable range).

RESULTS

<i>Nominal Concentration (mg/L)</i>	<i>Number of D. magna</i>	<i>Percent Immobilised (%)</i>	
		<i>24 h</i>	<i>48 h</i>
Control	15	0	0
100	15	0	0
180	15	0	0
320	15	0	93
560	15	0	100
1000	15	0	100

LC50 (95% confidence limits)

1000 mg/L at 24 hours
250 (180-320) mg/L at 48 hours

NOEC

180 mg/L at 48 hours

Remarks - Results

The OECD validity criteria were met.

The 48-hour median lethal dose was determined to be 250 mg/L with a 95% confidence interval of 320 mg/L to 1000 mg/L. Mortality, quiescence and/or daphnids on the bottom of the bottom of the test chamber were observed at 320, 560 and 1000 mg/L test solutions after 48 hours. Effects were not observed at test concentrations below 320 mg/L. Therefore, the no-observed-effect concentration was 180 mg/L.

CONCLUSION

The notified polymer is not harmful to aquatic invertebrates

TEST FACILITY

Analytical Biochemistry Laboratories Inc (1986b)

BIBLIOGRAPHY

- Analytical Biochemistry Laboratories Inc (1986a) Acute toxicity of [Notified polymer] to Bluegill Sunfish (*Lepomis macrochirus*) (Report No 34984, 27 August 1986). Columbia, Missouri, USA, Analytical Biochemistry Laboratories Inc, The Proctor and Gamble Company. (Unpublished report submitted by the notifier).
- Analytical Biochemistry Laboratories Inc (1986b) Acute toxicity of [Notified polymer] to *Daphnia magna* (Report No 34985, 26 August 1986). Columbia, Missouri, USA, Analytical Biochemistry Laboratories Inc, The Proctor and Gamble Company. (Unpublished report submitted by the notifier).
- MonoSol (2011) R&D Technical Report [notified polymer] Solubility (Report No 20111017, 17 October 2011). MonoSol, LLC. (Unpublished report submitted by the 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.
- NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia
- OWS Inc (1994) Aerobic Biodegradation Under Controlled Compositing Conditions of Quantification Substances [notified polymer] (Report No DJK-1, 17 June 1994). Dayton, Ohio, USA, O.W.S. Inc., The Proctor and Gamble Company. (Unpublished report submitted by the notifier).
- United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html>.
- US EPA (United States Environmental Protection Agency) (2007), Interpretive Assistance for the Assessment of Polymers, Updated 22 January 2007: <<http://www.epa.gov/oppt/sf/pubs/InterpretiveAssistancePolymers0107.pdf>> (Accessed 23 May 2012)
- US EPA (2011) Estimation Programs Interface (EPI) Suite™ for Microsoft® Windows, v 4.10. United States Environmental Protection Agency. Washington DC, USA, <<http://www.epa.gov/oppt/exposure/pubs/episuite.htm>>.
- Wildlife International, Ltd. (2002) [notified polymer]: Inherent Biodegradability by the Semicontinuous Activated Sludge (SCAS) Removability Test Method (Report No 106E 170, 28 August 2003). Easton, Maryland, USA, Wildlife International, Ltd., The Proctor and Gamble Company. (Unpublished report submitted by the notifier).
- Wildlife International, Ltd. (2003a) [notified polymer]: Carbon Dioxide Evolution Test Method (Report No 106E 167, 8 January 2003). Easton, Maryland, USA, Wildlife International, Ltd., The Proctor and Gamble Company. (Unpublished report submitted by the notifier).
- Wildlife International, Ltd. (2003b) [notified polymer]: Carbon Dioxide Evolution Test Method (Report No 106E 169, 30 May 2003). Easton, Maryland, USA, Wildlife International, Ltd., The Proctor and Gamble Company. (Unpublished report submitted by the notifier).