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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

PLA Polymer

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Director
Chemicals Notification and Assessment

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PLA Polymer

1. APPLICANT

Dow Chemical (Australia) Limited of 541-583 Kororoit Creek Road, Altona, Victoria 3018 (ACN 000 264 979) has submitted a limited notification statement in support of their application for an assessment certificate for PLA Polymer.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the polymer composition and details of exact import volume and customers have been exempted from publication in the Full Public Report and the Summary Report.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	clear, translucent or opaque pellets; sweet odour
Melting Point:	< 140°C
Specific Gravity:	1.25
Vapour Pressure:	not volatile
Particle Size:	pellets approximately 40 mg; dimensions not stated
Water Solubility:	approximately 20 mg/L at 20°C
n-Octanol Solubility:	slight, see comments below
Partition Co-efficient (n-octanol/water):	not determined
Hydrolysis as a Function of pH:	notified polymer hydrolyses in water; film weight decreased by 18.8 % at pH 10 and by 7.6 % at pH 4 and 7 over 11 days
Adsorption/Desorption:	not determined
Dissociation Constant:	no dissociable groups are present

Flammability:	not flammable; combustible
Explosive Properties:	not explosive
Reactivity/Stability:	soluble in halogenated solvents and ethers; toxic fumes produced above 230ºC; reacts with oxidising agents and strong bases; slowly hydrolyses in water

3.1 Comments on Physico-Chemical Properties

The water solubility was determined using a modified flask method (ABC Laboratories Inc., 2000a). The notified polymer (~250 mg) was weighed into water (250 mL), the solution was shaken for 72 h at 20ºC and filtered through pre-weighed filter paper. The filter paper was rinsed with water twice and dried at 100ºC for a total of 3 h. The entire procedure was repeated with initial polymer concentrations of 2000 and 5000 mg/L. The notifier reports that the above test indicates the notified polymer has water solubility of < 10 mg/L. However, analysis of the raw data indicates that the average solubility of the notified polymer is ~ 20 mg/L.

The partition coefficient of the notified polymer has not been determined due to its low water solubility and hydrophobic nature. The n-octanol solubility was determined using a modified flask method as described above for the determination of water solubility (ABC Laboratories Inc., 2000b). The test was conducted using a similar protocol to that described for the water solubility determination above. The replicate studies showed significant differences and the study authors concluded that the n-octanol solubility of the notified polymer is negligible. This suggests that the notified polymer is more soluble in the aquatic phase than the organic phase.

No adsorption/desorption tests were conducted for this notification. The notified polymer is expected to be immobile in soil due to its high molecular weight and expected low water solubility.

Although no tests were conducted, the notified polymer is unlikely to dissociate in the environmental pH range of 4 to 9 as it lacks acidic or basic functional groups.

4. PURITY OF THE CHEMICAL

Degree of Purity:	~ 90 %
Hazardous Impurities:	none are present at levels above the cutoff for classification of the notified polymer as a hazardous substance
Maximum Content of Residual Monomers:	none are present at levels above the cutoff for classification of the notified polymer as a hazardous substance

Additives/Adjuvants:	none are present at levels above the cutoff for classification of the notified polymer as a hazardous substance

5. USE, VOLUME AND FORMULATION

The notified polymer will be used in a variety of applications, and may be used as a replacement for a number of common polymers including polyesters, polyolefins, polystyrene and cellulosics. It may be fabricated by thermoforming, sheet and film extrusion, blow film processing, injection moulding and fibre spinning. In Australia, the proposed applications include food packaging and coated paper, containers (replacing PET and polypropylene) and fibres.

The notified polymer will be imported in pellet form, in 500 kg cartons or in bulk. The notifier anticipates that the import volume will be less than 100 tonnes per annum during the first five years of importation.

The notified polymer will be melt processed in Australia to produce articles such as packaging materials, containers and textiles.

6. OCCUPATIONAL EXPOSURE

Handling of the notified polymer will generally occur within automated enclosed systems. Local exhaust ventilation will be used throughout as required. For all workers, the maximum duration of exposure will be 8 - 12 hours per day, on a daily basis. The following details are per shift, with up to 3 shifts per day.

Transport and Storage
At each facility using the notified polymer, it is expected that one worker will be involved in receiving and storage of the notified polymer in pellet form. Bulk handling will involve a vacuum transfer system, with one worker supervising. The notifier indicated that safety glasses will be worn. Spilt pellets will be cleaned up as these pose a slip hazard; an air purifying respirator will be used if dusty conditions are anticipated.

No details of workers involved in unloading the notified polymer on the waterfront or in transport to the end use facilities were provided. However, due to the low bioavailability of the notified polymer in pellet form and as the handling will either be in enclosed bulk handling or as sealed containers, no exposure of these workers is expected.

Melt Processing
At each facility using the notified polymer, it is expected that two workers will be involved in feeding the notified polymer to the melt processing equipment and two workers will attend the equipment; a further worker may be involved in recycling the waste product.

The notified polymer will be transferred to the melt processing equipment from bulk store or from 500 kg cartons by vacuum transfer system. Additives such as colourants will be added at this stage. The melt processing equipment will be fully automated, and will be supervised

by two workers who will wear safety glasses, as well as leather gloves for protection against the elevated temperatures employed at this stage. Waste polymer will be collected automatically, and will go through a regrind stage, performed by one worker wearing safety glasses, and, if needed, respiratory protective masks. It will then be reintroduced to the melt processing equipment.

Product handling
The finished articles will be packaged in an automated process. One worker may be involved in handling coated paper or flexible films and other finished articles. Safety glasses are required.

7. PUBLIC EXPOSURE

Public exposure during transport and storage, processing and waste disposal is unlikely.

There will be a variety of final products containing the notified polymer. Substantial public exposure to the products containing the notified polymer is expected, particularly where the product is used for food packaging and clothing. In addition the public may be exposed to dust generated by cutting or grinding final products.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The notifier expects that approximately 40 kg per annum of the notified polymer will be released through spills. Spills will be collected and disposed of in a licensed waste landfill site.

Empty import cartons will be recycled while the carton liners containing residual polymer will be disposed of in landfill or incinerated.

The majority of the notified polymer will be incorporated into articles such as packaging, storage containers and fibre products and will eventually be disposed of in landfill.

8.2 Fate

Spills of the pelletised polymer will be collected and either reused or disposed of to landfill. Empty carton liners containing residual polymer will also be disposed of in landfill or incinerated, producing water vapour and oxides of carbon.

The notifier has produced three separate composting tests: an Aerobic Biodegradation Test under controlled composting conditions; a Pilot Scale Composting Test; and a Pilot Scale Composting and Sieving Test for Measurement of Disintegration.

An Aerobic Biodegradation Test was performed under controlled composting conditions (Organic Waste Systems N. V., 1997a). The biodegradation of the notified polymer was determined according to the ISO DIS 14855 method. The test was carried out using

amorphous and crystalline polymer samples at concentrations of 1 and 4.7 % of the notified polymer and included a cellulose standard. The inoculum was obtained from the organic fraction of municipal solid waste which had been further stabilised and matured in a composting bin under controlled aeration conditions. A set of 18 composting vessels each with a volume of 4 L were incubated at 58ºC for 90 days. The total cumulative CO_2 production was determined after 75 or 90 days. The percentage degradation of the cellulose reference after 90 days was approximately 92 % based on percent of potential carbon dioxide recovered. All test substances showed a lag phase of 2-3 weeks before biodegradation began. All samples were completely disintegrated and passed the 90 % degradation level for complete degradation, Samples A (4.7 %, amorphous PLA) and B (4.7 %, crystalline PLA) after 60 days, Sample C (1 %, amorphous PLA) after 70 days and Sample D (1 %, crystalline PLA) after 80 days of controlled composting. Intermediate breakdown products were not identified in testing.

A Pilot Scale Composting Test was conducted on the notified polymer (as EcoPLA spaghetti shaped material) under aerobic conditions (Organic Waste Systems N. V., 1997b). Fresh biowaste was derived from the organic fraction of municipal solid waste. The notified polymer was mixed with the biowaste and composted until fully stabilised compost was obtained (3 months) in a pilot scale-composting unit after which time the resulting compost was sieved and the disintegration of the polymer sample evaluated. The amount of notified polymer in the biowaste was 10 %. The temperature remained above 40ºC for 7 weeks and above 60ºC for 5 weeks. At completion of the test, the quality of the compost produced was similar to that of the control compost. However, the salt and nitrates content were higher. After 2 weeks the spaghetti shaped test substance had fragmented into small pieces (1 cm), after 6 weeks only traces were visible and after 10 weeks the test substance was not visible to the naked eye. The compost produced in this test was used in the ecotoxicity tests (Section 10).

A Pilot Scale Composting Test and Sieving Test for Measurement of Disintegration was conducted on the notified polymer (as EcoPLA cutlery) under aerobic conditions (Organic Waste Systems N. V., 1997c). Fresh biowaste was derived from the organic fraction of municipal solid waste. The notified polymer was mixed with the biowaste and composted until fully stabilised compost was obtained (3 months) in a pilot scale-composting unit after which time the resulting compost was sieved and the disintegration of the polymer sample evaluated. The amount of notifier polymer in the biowaste was 10 %, consisting of 1 % EcoPLA cutlery and 9 % EcoPLA powder. The temperature remained above 40ºC but below 75ºC for 4 weeks and above 60ºC for 3 weeks. At completion of the test, the quality of the compost produced was similar to that of the control compost. However, the nitrates content was higher. At the completion of the test the disintegration of the test substance was complete. The compost produced was also used in the ecotoxicity tests (Section 10).

Therefore it was concluded that the test polymer was biodegraded by microorganisms under the test conditions.

Manufacturing waste and notified polymer incorporated into final articles will eventually be disposed of in landfill. In landfill, the polymer is unlikely to be mobile in the soil environment due to its limited water solubility and will degrade to gases such as carbon dioxide through abiotic and biotic processes.

The large molecular weight and low water solubility of the notified polymer should prevent

bioaccumulation (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of PLA Polymer

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5000 mg/kg	(Hazleton Wisconson Inc., 1993b)
acute dermal toxicity	rabbit	LD_{50} > 2000 mg/kg	(Hazleton Wisconson Inc., 1993a)
skin irritation	rabbit	slight irritant	(Hazleton Wisconson Inc., 1993d)
eye irritation	rabbit	slight irritant	(Hazleton Wisconson Inc., 1993e)
skin sensitisation	guinea pig	non-sentitiser	(Hazleton Wisconson Inc., 1993c)

9.1.1 Oral Toxicity (Hazleton Wisconson Inc., 1993b)

Species/strain:	rat/Crl:CDBR
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage; notified polymer ground and mixed with corn oil; limit test 5000 mg/kg; dose volume 15 mL/kg
Test method:	40 CFR 798.1175
Mortality:	there were no premature decedents during the study
Clinical observations:	no clinical signs of toxicity were observed
Morphological findings:	multiple grey areas were observed on the parietal surface of the spleen for one animal; no other gross abnormalities were observed

Comment: the observations in the spleen in one animal were considered incidental and not related to treatment

LD_{50}: > 5000 mg/kg

Result: the notified polymer was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Hazleton Wisconson Inc., 1993a)

Species/strain: rabbit/Hra:(NZW)SPF

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: notified polymer, ground and moistened with 0.9 % saline was applied for 24 hr under occlusive conditions to a clipped area of the back; dose 2000 mg/kg

Test method: OECD TG 402, 40CFR 798.1100

Mortality: one female was found to have a broken back on day 1; this animal was euthanised, subjected to necropsy and replaced with an additional female; no other animals died during the study

Clinical observations: no clinical signs of systemic toxicity were observed

Morphological findings: no gross abnormalities were observed

Draize scores:

Time after treatment (days)	• *Animal #* ***1***♂	***2***♂	***3***♂	***4***♂	***5***♂	***6***♀	***7***♀	***8***♀	***9***♀	***10***♀*
Erythema [i]										
1	1	1	2	1	1	1	1	2	1	0
3	0	0	1	0	0	0	0	1	0	0
7	0	0	1	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0
Oedema	all Draize scores were zero									

[i] see Attachment 1 for Draize scales

Comment: *animal 10 was the replacement for the animal sacrificed on

	day 1; this animal had a score of 1 for erythema at this time
	erythema was observed on day 1 for all but one animal; this persisted beyond day 7 in one animal
LD_{50}:	> 2000 mg/kg
Result:	the notified polymer was of low dermal toxicity in rabbits

9.1.3 Skin Irritation (Hazleton Wisconson Inc., 1993d)

Species/strain:	rabbit/Hra:(NZW)SPF
Number/sex of animals:	3/sex
Observation period:	3 days
Method of administration:	notified polymer, ground and moistened with 0.9 % saline was applied for 4 hr under semi-occlusive conditions to a clipped area of the back; dose 0.5 g
Test method:	40 CFR 798.4470

Draize scores:

Time after treatment	***Animal #***					
	1 ♂	***2*** ♂	***3*** ♂	***4*** ♀	***5*** ♀	***6*** ♀
Erythema						
4 hr	[a]0	0	0	1	1	0
1 day	0	0	0	1	0	0
2 days	0	0	0	0	0	0
3 days	0	0	0	0	0	0
Oedema	all Draize scores were zero					

[a] see Attachment 1 for Draize scales

Result:	the notified polymer was slightly irritating to the skin of rabbits

9.1.4 Eye Irritation (Hazleton Wisconson Inc., 1993e)

Species/strain:	rabbit/Hra:(NZW)SPF
Number/sex of animals:	3/sex
Observation period:	3 days
Method of administration:	notified polymer, ground and passed through a 40 mesh

sieve, was instilled in the conjunctival sac of the right eye; the left eye served as control; dose 0.05 g (0.1 mL)

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation											
Animal	***1 hour***			***1 day***			***2 days***			***3 days***		
Cornea	all Draize scores were zero											
Iris	all Draize scores were zero											
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1♂	2	1	0	1	0	0	1	0	0	0	0	0
2♂	1	1	0	0	0	0	0	0	0	0	0	0
3♂	1	0	0	0	0	0	0	0	0	0	0	0
4♀	2	1	0	1	0	0	0	0	0	0	0	0
5♀	1	0	0	1	0	0	0	0	0	0	0	0
6♀	1	0	0	0	0	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge

Comment: two animals showed excessive pawing at the treated eye after instillation

Result: the notified polymer was slightly irritating to the eyes of rabbits

9.1.5 Skin Sensitisation (Buehler method) (Hazleton Wisconson Inc., 1993c)

Species/strain: guinea pig/Crl:(HA)BR

Number of animals: 10 male test and control groups

Induction procedure:

test group:
day 1, 8, 15 0.2 g notified polymer, ground and moistened with

	deionised water, was applied using an occlusive chamber to a clipped area of the back for 6 hours; residual material was removed with damp paper towel
control group: day 1, 8, 15	no treatment was given
Challenge procedure:	
day 29	0.2 g notified polymer was applied in a similar manner to the induction treatments for both the test and control animals
Test method:	40 CFR 798.4100 (Buehler method)
Comment:	no dermal responses were seen at challenge for any test or control animals
	a positive control, 0.3 % 2,4-dinitrochlorobenzene (DNCB) in 80 % ethanol was concurrently applied to 4 animals; dermal responses of similar magnitude were observed at induction and after challenge with 0.1 % DNCB in acetone
Result:	the notified polymer was not sensitising to the skin of guinea pigs

9.2 Overall Assessment of Toxicological Data

The notified polymer was of very low acute oral toxicity in rats (LD_{50} > 5000 mg/kg) and of low dermal toxicity in rabbits (LD_{50} > 2000 mg/kg). The notified polymer was a slight skin irritant in rabbits. Slight to moderate erythema was observed on day 1 after 24 hr occlusive application of the notified polymer in the dermal toxicity test. This persisted beyond day 7 in one animal. In a dermal irritation test in rabbits (4 hr occlusive exposure), slight erythema was observed at 4 hours, persisting in one animal beyond 24 hours. It was a slight eye irritant in rabbits, with conjunctival redness and chemosis observed at 1 hr after instillation; redness persisted beyond 24 hr in 3 animals and beyond 48 hr in one animal. The notified polymer was not a skin sensitiser in guinea pigs in a Buehler test.

No toxicology reports were submitted for other endpoints. Based on the toxicology data submitted by the notifier, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No test reports on the ecotoxicity studies for the notified polymer were provided. However, the notifier did present ecotoxicity reports for a number of samples of the composted PLA polymer.

Ecotoxicity Tests on Compost from biodegradation of EcoPLA Cutlery (See third study Section 8.2) (Organic Waste Systems N. V., 1997d):

Test	*Species*	*Results*
Growth Inhibition	Summer Barley Plant	No negative effect on germination or growth was observed in plants grown in a compost/soil mix containing an initial PLA polymer concentration of 10 % w/w biomass.
Growth Inhibition	Cress	No negative effect on germination or growth was observed in plants grown in a compost/soil mix containing an initial PLA polymer concentration of 10 % w/w biomass.
Acute Toxicity	Earthworm	No negative effect on survival and live weight was observed in mixing ratios of 15 and 30%. However, 100 % mortality was observed with mixing ratios of 60 %.
Acute Toxicity	Water Flea *Daphnia pulex*	Mortality was observed with dilutions below 1/32.

The summer barley plant growth test was performed in 500 mL flower pots containing a mixture of compost and standard soil. Both composted cellulose and PLA polymer were tested in two mixing ratios of compost and standard soil; 1/3 and 1/1 on a volumetric basis. The growth inhibition test was applied after a preceding composting test. At the beginning of the test each pot was filled with 400 mL of compost/soil mix or standard soil to which was added 100 mL of nutrient solution and 50 summer barley seeds. The seeds were covered with 100 mL of compost/soil mix or standard soil and watered with demineralised water. The pots were incubated at 22ºC with at least 12 h light per day for 10-12 days or until more than 50 % of the plants had developed a second leaf. At the end of the test the total fresh and dry weight of the soil plant material was determined for each pot. The notifier indicates that no negative effect on germination or growth was observed in summer barley plants grown in a compost/soil mix containing an initial PLA polymer concentration of 10 % (10 % notifier polymer/90 % biowaste by weight).

The cress plant growth test was performed in 500 mL flower pots containing a mixture of compost and standard soil. Both composted cellulose and PLA polymer were tested tested in two mixing ratios of compost and standard soil; 1/3 and 1/1 on a volumetric basis. The growth inhibition test was applied after a preceding composting test. At the beginning of the test each pot was filled with 480 mL of compost/soil mix or standard soil. A nutrient solution was added (100 mL) to the pot containing standard soil. Subsequently, 1 g of cress seeds was added to each pot and covered with 20 mL of white sand and watered with demineralised water. The pots were incubated at 22ºC with at least 12 h light per day for 7 days. At the end

of the test the total fresh and dry weight of the soil plant material was determined for each pot. The notifier indicates that no negative effect on germination or growth was observed in cress plants grown in a compost/soil mix containing an initial PLA polymer concentration of 10 % (10 % notifier polymer/90% biowaste by weight).

The acute earthworm toxicity test was performed in 1000 mL jars containing a mixture of compost and standard soil. Both composted cellulose and PLA polymer were tested in three mixing ratios of compost and standard soil; 15, 30 and 60 % on a wet weight basis. The acute earthworm toxicity test was applied after a preceding composting test. At the beginning of the test each jar was filled with 750 mL of compost/soil mix or standard soil to which were added 10 viable earthworms. The weight of the earthworms was determined before and after the test. The jars were incubated at 22ºC with continuous light for 14 days. The notifier indicates that there were no significant differences in the survival of earthworms between the standard soil, the cellulose compost and the PLA compost in the mixing ratios of 15 and 30 %. However, at a mixing ratio of 60 %, 100 % mortality was observed.

The acute daphnid toxicity test was performed in PVC multiwell test plates consisting of 6 wells (1 control and 5 test concentrations). Both composted cellulose and PLA polymer were tested. Tests were performed on compost eluants prepared by diluting 1 part compost with 4 parts leaching liquid (water). The resulting supernatant was further diluted with standard freshwater to give solutions containing 1/8, 1/16, 1/32 and 1/64 of the original solution. At the beginning of the test 5 mL of each of the 5 composting dilutions was transferred to the test wells and 5 daphnids were added to each well. The plates were incubated at 20ºC in darkness for 24 h. Both test solutions containing the cellulose and the PLA polymer compost eluant at 1/4 dilution exhibited 100 % daphnid mortality. The test solutions containing the cellulose compost eluant at 1/8 and 1/16 dilution exhibited 80 and 5 % daphnid mortality, respectively. The test solutions containing the PLA polymer compost eluant at 1/8 and 1/16 dilution exhibited 90 and 13 % daphnid mortality, respectively, indicating only slightly, if any, enhanced toxicity. No mortality was observed in the test solutions containing the cellulose and the PLA polymer compost eluant at 1/32 dilution or lower.

The ecotoxicity data indicates the degradation products of the notified polymer are not toxic to earthworms and daphnia in compost and compost eluant containing the notified polymer at an initial concentration of 10 %, as the toxicity observed was virtually identical to that of the reference compost. Similarly, the germination and growth of summer barley and cress plants was not inhibited when grown in compost containing the notified polymer at an initial concentration of 10 % (10 % notifier polymer/90 % biowaste by weight).
Ecotoxicity Tests on Compost from biodegradation of EcoPLA (See second study Section 8.2) (Organic Waste Systems N. V., 1997e):

Test	***Species***	***Results***
Growth Inhibition	Summer Barley Plant	No negative effect on germination or growth was observed in plants grown in a compost/soil mix containing an initial PLA polymer concentration of 10 % (10 % notifier polymer/90 % biowaste by weight).
Growth Inhibition	Cress	No negative effect on germination

		or growth was observed in plants grown in a compost/soil mix containing an initial PLA polymer concentration of 10 % (10 % notifier polymer/90 % biowaste by weight).
Acute Toxicity	Earthworm	No negative effect on survival and live weight was observed in mixing ratios of 20 and 30 %. However, 63 % mortality was observed with mixing ratios of 60%.
Acute Toxicity	Water Flea *Daphnia magna*	Mortality was observed with dilutions below 1/32.

The summer barley plant growth test was performed as described above. The notifier indicates that no negative effect on germination or growth was observed in summer barley plants grown in a compost/soil mix containing an initial PLA polymer concentration of 10 %.

The cress plant growth test was performed as described above. The notifier indicates that no negative effect on germination or growth was observed in cress plants grown in a compost containing an initial PLA polymer concentration of 10 % (10 % notifier polymer/90 % biowaste by weight).

The acute earthworm toxicity test was performed as described above, with composted cellulose and PLA polymer using mixing ratios of compost and standard soil of 20, 35 and 60 % on a wet weight basis. The notifier indicates that there were no significant differences in the survival of earthworms between the standard soil, the cellulose compost and the PLA compost in the mixing ratios of 20 and 35 %. However, at a mixing ratio of 60 %, 63 % mortality was observed.

The acute daphnid toxicity test was performed as described above. Both test solutions containing the cellulose and the PLA polymer compost eluant at 1/4 dilution exhibited 100 and 93 % daphnid mortality, respectively. The test solutions containing the cellulose compost eluant at 1/8 and 1/16 dilution both exhibited 100 % daphnid mortality. The test solutions containing the PLA polymer compost eluant at 1/8 and 1/16 dilution exhibited 25 and 2 % daphnid mortality, respectively. No mortality was observed in the test solutions containing the cellulose and the PLA polymer compost eluant at 1/32 dilution or lower.

The ecotoxicity data indicates the degradation products of the notified polymer are not toxic to earthworms and daphnia in compost and compost eluant containing the notified polymer at an initial concentration of 10 %, as the toxicity observed was less than that of the reference compost. Similarly, the germination and growth of summer barley and cress plants was not inhibited when grown in compost containing the notified polymer at an initial concentration of 10 % (10 % notifier polymer/90 % biowaste by weight).

Ecotoxicity Tests on Compost from biodegradation of EcoPLA Cups (Organic Waste Systems N. V., 1997f):

Test	*Species*	*Results*
Growth Inhibition	Summer Barley Plant	No negative effect on germination or growth was observed in plants grown in a compost/soil mix containing an initial PLA polymer concentration of 10 % (10 % notifier polymer/90 % biowaste by weight).
Growth Inhibition	Cress	No negative effect on germination or growth was observed in plants grown in a compost/soil mix containing an initial PLA polymer concentration of 10 % (10 % notifier polymer/90 % biowaste by weight).
Acute Toxicity	Earthworm	No negative effect on survival and live weight was observed in mixing ratios of 20 and 30 %. However, 63 % mortality was observed with mixing ratios of 60 %.
Acute Toxicity	Water Flea *Daphnia magna*	Some mortality was observed at all dilutions.

The summer barley plant growth test was performed as described above. The notifier indicates that no negative effect on germination or growth was observed in summer barley plants grown in a compost/soil mix containing an initial PLA polymer concentration of 10 % (10 % notifier polymer/90 % biowaste by weight).

The cress plant growth test was performed as described above. Both composted cellulose and PLA polymer and standard soil were tested in 4 replicates. The notifier indicates that no negative effect on germination or growth was observed in cress plants grown in a compost containing an initial PLA polymer concentration of 10 % (10 % notifier polymer/90 % biowaste by weight).

The acute earthworm toxicity test was performed as described above, with composted cellulose and PLA polymer using mixing ratios of compost and standard soil of 40, 65 and 100 % on a wet weight basis. The notifier indicates that there were no significant differences in the survival of earthworms between the standard soil, the cellulose compost and the PLA compost in the mixing ratios of 40 and 65%. However, at a mixing ratio of 100 %, 17 % mortality was observed with PLA compost. By comparison, mortality observed in the standard mixtures of 40, 65 and 100 % was 100, 13 and 0 %, respectively.

The acute daphnid toxicity test was performed as described above. Both test solutions containing the cellulose and the PLA polymer compost eluant at 1/4 dilution exhibited 52 and 45 % daphnid mortality, respectively. The test solutions containing the cellulose compost eluant at 1/8 and 1/16 dilution exhibited 20 and 10 % daphnid mortality, respectively. The test solutions containing the PLA polymer compost eluant at 1/8 and 1/16 dilution exhibited 8

and 13% daphnid mortality, respectively. The test solutions containing the cellulose compost eluant at 1/32 and 1/64 dilution exhibited 12 and 3 % daphnid mortality, respectively. The test solutions containing the PLA polymer compost eluant at 1/32 and 1/64 dilution exhibited 18 and 12 % daphnid mortality, respectively, indicating only slightly enhanced toxicity.

The ecotoxicity data indicates the degradation products of the notified polymer are not toxic to earthworms and daphnia in compost and compost eluant containing the notified polymer at an initial concentration of 10 %, as the toxicity observed was virtually identical to that of the reference compost. Similarly, the germination and growth of summer barley and cress plants was not inhibited when grown in compost containing the notified polymer at an initial concentration of 10 % (10 % notifier polymer/90 % biowaste by weight).

Ecotoxicity Tests on Compost from biodegradation of four PLA Polymer composts (Organic Waste Systems N. V., 1997g):

Test	***Species***	***Results***
Growth Inhibition	Summer Barley Plant	No negative effect on germination or growth was observed in summer barley plants grown in a compost/soil mix initially containing the notified polymer.
Inhibition of Germination	Cress	No significant negative effect on germination could be established for the three concentrations studied
Acute Toxicity	*Brachionus calyciflorus*	No negative effect on survival was observed in tests containing the degradation products of the notified polymer when compared with the control and cellulose compost.
Acute Toxicity	*Thamnocephalus platyurus*	No negative effect on survival was observed in tests containing the degradation products of the notified polymer when compared with the control and cellulose compost.

The summer barley plant growth test was performed as described above. The notifier indicates that no negative effect on germination or growth was observed in summer barley plants grown in a compost/soil mix initially containing the notified polymer.

The cress plant germination test was performed in a Petri dish containing filter paper to which composting eluant had been added. The composting eluant was prepared by taking one part compost and shaking it with 5 parts water for 1 h after which the resulting suspension was centrifuged (20 min, 4000 rpm) and filtered. Portions of the supernatant were diluted two and four times. The supernatant, 1/2 dilution, 1/4 dilution and distiled water were added to separate Petri dishes and 15 cress seeds were added and left to germinate in the dark at room

temperature for 4 days. The notifier indicates that no significant negative effect on germination could be established for the three concentrations studied.

The *Brachionus calyciflorus* (a rotifer) toxicity test was performed in multiwell test plates consisting of 6 wells (1 control and 5 test concentrations). Both composted cellulose and PLA polymer were tested. Tests were performed on compost eluants prepared by diluting 1 part compost with 4 parts leaching liquid (water). The resulting supernatant was further diluted with standard freshwater to give solutions containing 1/8, 1/16, 1/32 and 1/64 of the original solution. At the beginning of the test 5 mL of each of the 5 composting dilutions was transferred to the test wells and 5 rotifers were added to each well. The plates were incubated at 20ºC in darkness for 24 h. The percentage mortality observed in the tests are shown below.

		Mortality (%)				
Treatment	***neat***	***1/4***	***1/8***	***1/16***	***1/32***	***1/64***
Freshwater control	11					
Control compost		100	83	27	10	20
Cellulose compost		100	90	23	0	3
Test compost #1		100	47	16	10	3
Test compost #2		100	63	7	3	0
Test compost #4		100	37	3	3	7
Test compost #5		100	100	100	3	3

The acute *Thamnocephalus platyurus* (a crustacean) toxicity test was performed as described above for the *Brachionus calyciflorus* toxicity test. The percentage mortality observed in the tests are shown below.

		Mortality (%)				
Treatment	***neat***	***1/4***	***1/8***	***1/16***	***1/32***	***1/64***
Freshwater control	2					
Control compost		100	100	23	13	7
Cellulose compost		100	100	10	0	0
Test compost #1		100	100	30	7	3
Test compost #2		100	63	7	3	0
Test compost #4		100	37	3	3	7
Test compost #5		100	100	100	3	3

The ecotoxicity data indicates the degradation products of the notified polymer are not toxic to *Brachionus calyciflorus* and *Thamnocephalus platyurus* when compared with the control and cellulose compost except for Test compost #5 which exhibited substantially higher toxicity at 1/16 dilution. Similarly, the germination and growth of summer barley and the germination of cress plants were not inhibited when grown in compost containing the

degradation products of the notified polymer, when compared with the control and cellulose compost.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Spills of the pelletised polymer will be collected and either reused or disposed of to landfill. Empty carton liners containing residual polymer will also be disposed of in landfill or incinerated. Incineration would produce water vapour and oxides of carbon.

The notifier has produced three separate composting tests: an Aerobic Biodegradation Test under controlled composting conditions; a Pilot Scale Composting Test; and a Pilot Scale Composting and Sieving Test for Measurement of Disintegration. The aerobic biodegradation test indicated the percentage degradation of cellulose after 90 days was approximately 92 %. After the same period the notified polymer degraded up to 95.5 %. Therefore, the notified polymer was biodegraded by microorganisms under the test conditions. All three tests indicate that, under composting conditions, the notifier polymer completely disintegrates with in 90 days.

Manufacturing waste and notified polymer incorporated into final articles will eventually be disposed of in landfill. In landfill, the polymer is unlikely to be mobile in the soil environment due to its limited water solubility and is expected to degrade to gases such as carbon dioxide through abiotic and biotic processes.

The large molecular weight and low water solubility of the notified polymer should prevent bioaccumulation (Connell, 1990).

The ecotoxicity data indicates the degradation products formed during the composting of samples of several different forms of the notified polymer are no more toxic to earthworms, daphnia, the rotifer *Brachionus calyciflorus* and the crustacean *Thamnocephalus platyurus* than control and cellulose compost and compost eluant. Similarly, the germination and growth of summer barley and the germination of cress plants are not inhibited when grown in compost containing the degradation products of the notified polymer, when compared with control and cellulose compost.

Therefore, the environmental exposure and overall environmental hazard from the notified polymer is expected to be low

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer is of very low oral toxicity in rats and low dermal toxicity in rabbits, and is a slight skin and eye irritant to rabbits. The MSDS for the notified polymer indicates that moderate eye irritation may occur on acute exposure. It is not a skin sensitiser in guinea pigs. For the endpoints tested, the notified polymer is not classified as a hazardous substance in accordance with the Approved Criteria.

Occupational Heath and Safety
Little occupational exposure to the notified polymer is likely due its physical form (pellets or

fabricated fibres, sheets or articles). In these forms the notified polymer is unlikely to be bioavailable. Handling is generally automated and enclosed. Should dusts occur, ocular exposure is possible, and safety glasses should be worn. A dust mask or respirator should be used in very dusty conditions. The NOHSC exposure standard for dusts in general of 10 mg/m^3 (NOHSC, 1995) should be adhered to in handling the notified polymer in powder form.

The pellets pose a slip hazard, and should be cleaned up immediately. Processing involves elevated temperatures, and precautions should be taken where newly fabricated polymer products are handled. Toxic fumes may be generated if the notified polymer is overheated (> 230^{o}C), and precautions should be taken to prevent overheating; respiratory protection may be required should decomposition products be formed.

Public Health
Public exposure to the notified polymer will be through contact with moulded products, however, in this form it is not bioavailable. Chewing, in particular by children, of the products and raw pellet form, which could be mistaken for lollies, is not likely to pose a significant toxicological risk due to the very low oral toxicity. The use of the polymer in food containers is not likely to pose a threat to public health as the oral toxicity is very low and very little of the notified polymer would become available in the food. Similarly the use in textiles, particularly clothing, is unlikely to pose a public health threat due to the low dermal toxicity and skin irritancy of the polymer. Dust generated through cutting or grinding will render the polymer bioavailable, however, as it is of low toxicity and a low skin and eye irritant, it is unlikely to pose a significant public health hazard.

13. RECOMMENDATIONS

Control Measures

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - The NOHSC exposure standard for dusts in general of 10 mg/m^3 should be adhered to in handling the notified polymer in powder form; if work practices and engineering controls do not reduce exposure to dust or thermal decomposition products sufficiently, respiratory protection should be used;
  - Spillages are a slip hazard and should be swept up promptly and put into containers for disposal.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Protective eyewear, industrial clothing and footwear should be used during occupational handling of the notified polymer.

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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

13.1 Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

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Organic Waste Systems N. V. (1997g), Ecotoxicity Tests of Control compost, Cellulose compost, [four test composts], Gent, Belgium, (unpublished report).

Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

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