

File No PLC/606

June 2006

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

FULL PUBLIC REPORT

Polymer in Tegomer C-Si 2342

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 and Heritage.

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**Director
NICNAS**

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FULL PUBLIC REPORT**Polymer in Tegomer C-Si 2342****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

International Sales and Marketing Pty Ltd (ABN: 36 467 259 314)
262 Highett Road
Highett VIC 3190

TFL Australia (ABN: 58 075 730 166)

122-124 Errol Street
North Melbourne VIC 3051

NOTIFICATION CATEGORY

Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Spectral data

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA TSCA (2002)
Canada DSL (2002)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Polymer in Tegomer C-Si 2342
Drywalk FAT (product containing the notified polymer)

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)	>1000
Weight percentage of polymer species with MW <1000	<10%

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

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

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported both as a component of a finished leather treatment formulation (Drywalk FAT) by TFL Australia, and as the neat polymer by International Sales and Marketing Pty Ltd (Melbourne). Each notifier will import roughly equal proportions of the notified polymer.

The neat liquid polymer will be imported in 25 kg and 200 kg drums. The Drywalk FAT will be imported in 110 kg drums and 900 kg Schutz containers (tanks).

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	10	10	10	10	10

USE

Hydrophobising agent for use during leather treatment.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

Following import, the notified polymer in Tegomer C-Si 2342 will be distributed directly to various industrial customers for use in leather treatment. The notified polymer is a component of wet-process formulations, at a level between 4 and 10%. Besides the notified polymer, these formulations include organic fatliquoring agents (anionic modified oils), mineral oils and anionic or non-ionic emulsifiers.

Reformulation

There are currently only future plans to reformulate Tegomer C-Si 2342 into a leather treatment product. When this occurs it is likely to involve transfer from 200 kg or 1000 kg containers via a drum pump or drum lifting equipment and gravity feed to the mixing vessel. Once blended at approximately 9%, the formulated product would need to be sampled for quality control and then decanted into drums. The final product would be marketed in 200 kg drums or 1000 kg Intermediate Bulk Containers.

End use

The wet-process formulations are used during leather post-tanning, dyeing or fatliquoring, at about 5% based on skin/hide weight. A pump will transfer the formulation containing the notified polymer to a dipping vat where leather will be soaked for a period of time. During this time the notified polymer reacts with functional groups in the leather substrate, to permanently hydrophobise the leather. An exhaustion rate of 97-100% binding of notified polymer to leather is expected. Once the dipping of the leather is completed, the leather is removed from the vat, and allowed to dry.

TFL Drywalk FAT will be imported to and stored at Patrick Intermodal, 180 Fitzgerald Road, Laverton, Victoria, for dispatch directly to leather industry customers.

6. EXPOSURE INFORMATION

6.1. Summary of Occupational Exposure

Transport workers and a storeman would only be exposed to the notified chemical in the case of an accident or spill when packaging is accidentally breached.

Reformulation

Exposure of 2 operators for 2 hours per week may occur during transfer of Tegomer C-Si 2342 to the mixing vessel. Appropriate personal protective equipment is normally used by these workers to control exposure. Exposure of quality control workers and the operators involved in drumming off can occur but the concentration of notified chemical is now low.

End use

Production workers (6 workers) will wear skin/eye PPE and undertake safe work practices. Dermal and ocular exposure could occur. However, the transfer of formulations containing the notified polymer to the dosing system is via piping, and workers will only face exposure while they open tanks and attaching the piping. Exposure to significant amounts of the notified polymer is limited because of the personal protective equipment worn by workers, and because the possibility of exposure occurs only once per month, when the Schutz container is connected.

The treatment of leather is an automated process. Once dried, the leather containing the notified polymer is inert and unavailable to cause worker exposure.

6.2. Summary of Public Exposure

Members of the public will not use the notified polymer in its neat form. Leather that has been treated with the notified polymer will be sold to the public, predominantly as shoe leather. This is the only route by which the public might be exposed. However, as the notified polymer is fixed permanently to the leather, it presents a low risk of leaching during use. In addition, the notified polymer has a molecular weight > 1000 and is therefore unlikely to be bioavailable. Therefore, any public exposure to the notified polymer is considered to be very low.

6.3. Summary of Environmental Exposure

6.3.1. Environmental Release

Losses to the environment from local formulation are not detailed but these are not likely to be greater than 5% from spills, cleaning equipment and residues in import containers. Container residues are expected to be rinsed and added to the processing tanks, with minimal release of the chemical to the environment. Any losses are likely to be collected and disposed by authorised incineration or landfill.

The notified chemical will be released at the site of use in small amounts due to incomplete fixing of the chemical to the leather products during their manufacture. It is estimated that 3% of the polymer is not fixed to the leather. It is conservatively estimated that the bath will be emptied after 10 batches of dipping with regeneration in between. Accordingly only 0.3% of the polymer introduced will be disposed of during processing. An oil phase is removed before the release to sewer and it is expected that a high proportion of the notified chemical will remain in this phase due to its hydrophobicity. No specific indication is given to how this phase is disposed, however it is expected that it would be appropriately incinerated releasing oxides of carbon, water vapour and silicon dioxide. In a worst case scenario where minimal polymer is retained in the oil phase then it is expected that 30 kg of the 10 tonnes of polymer used in processing per annum will be released to the sewer.

The vast majority of the polymer will be released to the environment at the end of the useful life of the leather product. The products such as shoes will be landfilled and the polymer is expected to largely remain bound to the leather.

Release during transport and from storage facilities is expected to be minimal provided correct procedures are followed.

6.3.2. Environmental Fate

No environmental fate data are provided. The chemical is unlikely to bioaccumulate or readily biodegrade due to its high molecular weight and its hydrophobicity. The chemical's bioavailability is expected to be limited. Any notified polymer released to the aquatic environment is expected to be persistent.

The majority of the notified polymer's fate is associated with the fate of the leather products. The polymer will be landfilled with eventual degradation to water vapour, oxides of carbon, landfill gases such as methane and silica by biotic and abiotic processes.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Yellowish liquid with a specific odour
Boiling Point (degradation point)	250 - 300°C (based on similar polymers used by the notifier)
Density	990 kg/m ³ at 25°C
Water Solubility	Insoluble in water. Forms a separate phase.
Dissociation Constant	Contains anionic groups, which are expected to have typical acidity, with pKa 4 - 5.
Flash Point	129°C
Reactivity	Stable under normal environmental conditions. Although hydrolysable groups are present no hydrolysis is expected in the normal pH range 4-9. Not expected to be oxidising, based on structure.
Degradation Products	None under normal conditions of use.

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity	No	Yes ¹
Rabbit, skin irritation	slightly irritating	No	Yes ²
Rabbit, eye irritation	non-irritating	No	Yes ³

All results were indicative of low hazard.

8.1.1. Discussion of observed effects

- After oral dosing at 2000 mg/kg bw (but not at 200 mg/kg bw), diarrhoea was observed in two male and 3 female animals. This had resolved by 24 hours post-application.
- Mild skin irritant, based on the induction of slight, transient erythema (in two animals at 1 hour post application and in all animals 4 hours post application). All effects had resolved after 24 hours. This was not sufficient for it to be classified as an irritant in the EU.
- Slight redness of the conjunctivae and slight chemosis were observed in all animals one hour after application of the notified polymer. All rabbits' eyes were normal from 24 hours onwards.

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by the available toxicological data.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

The following toxicological studies were submitted:

<i>Endpoint</i>	<i>Result and Conclusion</i>
-----------------	------------------------------

Daphnia ToxicityEC0 100 mg/L (WAF)

A water accommodated fraction (WAF) was prepared by adding 100 mg of test substance to 1 L of dilution water, stirred for 24 hours at room temperature and poured through a folded filter. The total carbon (TC) of the dilution water was 19.6 mg/L and the TC content of the test solution was 19.7 mg/L. The solubility of the polymer was not calculated, as it was below the detection limit of the TC method employed. The test substance was considered non-toxic to *Daphnia* to the limits of its solubility.

9.2. Environmental Hazard Assessment

Polymers containing anionic groups are known to be moderately toxic to algae. The mode of toxic action is overchelation of nutrient elements needed by algae for growth (Nabholz *et al.* 1993). Only the terminal groups of the polymer contain anionic groups. Consequently the level of chelation is expected to be low. The toxicity to algae is likely to be further reduced due to the presence of calcium ions, which will bind to the functional groups and the hydrophobicity of the polymer. The aquatic toxicity is therefore expected to be low.

10. RISK ASSESSMENT

10.1. Environment

An estimated 30 kg of polymer is expected to be released during manufacture of leather products containing the notified polymer. The release is expected to occur in a batch wise manner. Each batch for disposal is expected to contain 3% of the treatment medium, which is a up to 10% solution of the polymer. From a 1000 L dipping bath 2.7 kg is expected to be released to sewer typically in one day, approximately eleven times per annum. A worst case scenario is assumed wherein no polymer reports to the oil phase and no polymer is removed during on- site water treatment. Although no details are given to the identity of the customer, a likely worst case scenario would involve a manufacturer in rural Victoria. In this case, where the polymer is processed in the sewage treatment works (5 ML per day) a PEC of 540 µg/L in the effluent is calculated.

Insufficient data are provided to calculate a PNEC. However, no effect was demonstrated on the single environmental toxicology test performed up to the limit of the solubility of the polymer. Due to the insolubility of the polymer it is unlikely that the polymer will enter the aquatic compartment in sufficient concentration to have an adverse effect. It is therefore considered that the risk to the aquatic environment is acceptable.

The majority of the polymer will be disposed of to landfill at the end of the useful life of the leather products. It will remain bound to the leather until eventually degrading to form landfill gases (such as methane and oxides of carbon), water vapour and silica.

Minor quantities arising from spills are expected to be adsorbed and incinerated releasing oxides of carbon, water vapour and silica which will report to the ash; or will be adsorbed to soil where it is likely to be immobile due to its hydrophobicity.

10.2. Occupational Health and Safety

The OHS risk presented by the notified polymer is expected to be low, given its apparent low toxicity and assuming appropriate PPE is used. The notified polymer may be present in formulations containing hazardous ingredients. If these formulations 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.

10.3. Public Health

The notified polymer will not be available to the public in its imported form. Members of the public will make dermal contact with leather products that have been treated with the notified

polymer. However, the risk to public health will be negligible because the notified polymer is permanently bound to leather items, and will not be bioavailable. Therefore, given its low toxicity, the use of the notified polymer in the treatment of leather presents a low risk to public health.

11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

11.1. Environmental Risk Assessment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

11.2. Human Health Risk Assessment

11.2.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

11.2.2. Public health

There is No Significant Concern to public health when the notified polymer is used in the proposed manner.

12. MATERIAL SAFETY DATA SHEET

12.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

13. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.
 - Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the 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.

Disposal

- The notified polymer should be disposed of by authorised landfill or incineration.

Emergency procedures

- Spills/release of the notified polymer should be handled by physical containment with subsequent adsorption (diatomaceous earth, vermiculite, sand etc) and disposal by authorised incineration or landfill.

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

or

- (2) Under subsection 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.