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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

POLYMER IN E7844

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Director
NICNAS

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POLYMER IN E7844

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Afton Chemical Asia Pacific LLC (ABN 99 109 644 288) of Level 9, 20 Berry Street, North Sydney NSW 2059.

NOTIFICATION CATEGORY
Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical identity and composition
Import volume
Import concentration

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting point/ boiling point
Vapour pressure
Hydrolysis as function of pH
Partition coefficient
Adsorption/desorption
Dissociation constant
Particle size
Flash point

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada, European Union, Japan, Korea, Philippines, China

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymer in E 7844

3. COMPOSITION

DEGREE OF PURITY
<80 %

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
Yes

ADDITIVES/ADJUVANTS
None

DEGRADATION PRODUCTS
None. On combustion produces oxides of carbon, nitrogen and hydrogen.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED POLYMER (100%) OVER NEXT 5 YEARS
Import of polymer solution, no manufacture envisaged.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<300	<300	<300	<300	<300

USE
The notified polymer will be used as an additive in automotive fuels at less than 1%.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney, Melbourne, Brisbane and Perth

IDENTITY OF MANUFACTURER/RECIPIENTS
Afton Chemical Asia Pacific LLC

TRANSPORTATION AND PACKAGING
The notified polymer will be imported as a component of the product E7844 (60-100% notified polymer) in 20-ton ISO closed containers. The containers will be transported from the port of entry directly to the customer(s) warehouses by road transport.

5.2. Operation description

Manufacture
The notified polymer is not manufactured in Australia. The notified polymer will be imported as a component of the fuel additive formulation E7844.

Shipping and Transport
The fuel additive formulation containing the notified polymer will be received in 200-ton ISO containers and transported to customer sites, where the contents will be transferred by pipe to the manufacturing process unit. Automated processes and dedicated delivery lines and equipment are used for this activity.

Reformulation
The imported fuel additive formulation containing the notified polymer will be blended with fuel in a fully automated, dedicated and enclosed system to make a blended fuel.

Distribution and use
The blended fuel containing the notified polymer will be distributed by road tankers for delivery and sale at retail fuel outlets.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Operations and maintenance	100	8 hours	365
Storage	24	4 hours	365
Transport	20	8 hours	80

Exposure Details

Import, transport and distribution
Import, transport and distribution workers may be inadvertently exposed to the notified polymer in the case of any accidental packaging breach or unintentional release of blended fuel.

Fuel blending
Operations workers at customer sites will be potentially exposed to the notified polymer during fuel blending. At the customer site, the processing unit operates in continuous mode. The fuel additive formulation containing the notified polymer is transferred to the processing unit by means of fixed lines and the blended fuel containing the notified polymer is piped similarly by means of fixed lines to refinery storage tanks. The handling of the product is similar to the handling of fuel. As required, the blended fuel containing the notified polymer is transferred via fixed/enclosed pipes and transfer lines to road fuel tankers for delivery of the blended fuel to customer sites. The workers use personal protection equipment (PPE) such as chemical resistant gloves, boots, chemical goggles or face shields, and long sleeves.

Fuel use
While the notifier provides no specific details, petrol station workers and mechanics at service stations and maintenance workshops may be potentially exposed to diluted notified polymer in fuel during fuel handling activities and maintenance of automotive fuel systems.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Fuel blending
No release of the notified polymer is expected at the customer site during transport and blending, except in the event of an accidental spill. Any spills occurring during blending operations are to be contained by inert material and collected for disposal by incineration. The notifier has indicated the customer will be using a fully automated and closed blending unit, which controls and monitors the blending process and includes safety features such as spill containment and explosion-proof controls.

A maximum of 4% of the notified polymer may remain in the import containers after emptying. This equates to less than 12 tonnes per year, assuming the maximum yearly import volume. The majority of these residues will be in isotainers which will be returned for reuse. Drums and any residual product will be sent to reconditioning facilities where the drums are to be rinsed and the residues disposed of through an aqueous treatment plant and the rinsate disposed of in accordance with government regulations.

RELEASE OF CHEMICAL FROM USE
Fuel use
No significant release of the notified polymer is expected at end use because the notifier expects the substance will be consumed in the automotive engine along with the petrol fuel to generate primarily carbon dioxide and water, with small amounts of nitrogen oxides. Assuming that on average 10 mL of petrol is spilled at each fill and assuming maximum import volumes, this corresponds to < 100 kg per annum of the notified polymer being lost through spills while re-fuelling vehicles. These spills would be distributed across a maximum of 1500 service stations, which it is estimated may be selling fuel containing the notified polymer.

5.5. Disposal
Incineration is the recommended disposal method. For spills occurring on land, the liquid can be collected for recycling or disposal with any residues absorbed and incinerated. For spills on water the notified polymer can be skimmed from the water surface onto absorbent material and incinerated.

5.6. Public exposure
Fuel blending
The notified polymer itself will not be available to the public. The notified polymer will be available to the public only after it has been mixed with fuel at the refinery.

Fuel use
Members of the public may come into contact with fuel containing the notified polymer. As the blended fuel containing the notified polymer will be available through normal retail outlets, wide spread public exposure to the notified polymer via fuel is likely to occur. It is difficult to quantify the level of exposure likely to be encountered during public end-use of fuel. Nonetheless, it is expected that consumer exposure is likely to be a regular occurrence for vehicle owners, e.g. weekly, take place under open conditions and involve small quantities per event. Given the low concentration (<1%) and the minimal direct contact with fuel under normal circumstances, public exposure is expected to be incidental and minimal.

6. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer is not isolated from the solvent.

Appearance at 20°C and 101.3 kPa Amber viscous liquid (as prepared in the solvent)

Melting Point/Freezing Point Not determined

Remarks Polymer is not isolated from solvent.

Boiling Point Not determined

Remarks Polymer is not isolated from solvent.

Specific Density 0.910 at 15.6°C (notified polymer in solvent).

Remarks
TEST FACILITY

Vapour Pressure Not measured

Remarks Notified polymer has high molecular weight and present in solvent. Based on the high molecular weight, the notified polymer is not expected to be volatile.

Water Solubility < 1ppm

METHOD OECD TG 105 Water Solubility.
Remarks Column Elution Method, UV detection. All collected fractions contained less than 1 ppm of the notified polymer.
TEST FACILITY Ethyl Petroleum Additives USA

Hydrolysis as a Function of pH Not determined

METHOD
Remarks Polymer is not water soluble. The polymer does not contain functional groups which are susceptible to hydrolysis.
TEST FACILITY

Partition Coefficient (n-octanol/water) log Pow > 5.68 (calculated)

METHOD
Remarks The value was estimated from the ratio of the limit values for the solubilities of the polymer in octanol and water.
TEST FACILITY

Adsorption/Desorption Not determined

METHOD
Remarks Low water solubility prevents experimental determination. Based on the low water

solubility and high partition coefficient the notified polymer is expected to bind strongly with soils and sediments.

TEST FACILITY

Dissociation Constant Not determined

METHOD
Remarks Low water solubility prevents experimental determination. The notified polymer contains functionalities which would be expected to display typical basicity.
TEST FACILITY

Particle Size Not relevant

METHOD
Remarks Polymer is not isolated from solvent
TEST FACILITY

Flash Point > 40°C (as present in solvent)

METHOD Closed cup
Remarks Relates to solvent in product.
TEST FACILITY Taken from MSDS

Flammability Limits Not determined.

Remarks Combustible as formulated. Polymer is not isolated from solvent
TEST FACILITY

Autoignition Temperature Not determined

METHOD
Remarks Polymer is never separated from solvent.

Explosive Properties None

METHOD
Remarks No chemical groups present that would imply explosive properties. .
TEST FACILITY

Reactivity

Remarks The notified polymer is expected to be stable under normal environmental conditions. Avoid strong oxidising and reducing agents.

7. TOXICOLOGICAL INVESTIGATIONS

Data from acceptable analogue chemicals (A and B) are summarised below. The analogues are of the same chemical class (alkyl phenol alkyl amine) as the notified polymer. The chemical identity of analogues is exempt information.

Endpoint and Result	*Assessment Conclusion*
Rabbit, skin irritation (Analogue A)	irritating
Rabbit, eye irritation (Analogue A)	slightly irritating
Rat, acute oral toxicity (Analogue B)	LD50 > 5000 mg/kg bw/day
Ames Mutagenicity (Analogue B)	Not mutagenic
Micronucleus cytogenetic assay (Analogue B)	Negative cytogenetic assay
Two Generation study	NOAEL (reproductive) 1000 mg/kg bw/day

7.1. Acute toxicity – oral

TEST SUBSTANCE	Analogue B
METHOD	OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/Sprague Dawley
Vehicle	Corn Oil
Remarks - Method	No significant protocol deviations. The notified polymer was administered as a single dose of 5 g/kg at 10mL/kg bw dosing volume.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	5000	None

LD50	> 5000 mg/kg bw
Signs of Toxicity	Most animals showed initial systemic toxicity, such as respiration changes, flattened and/or hunched posture, lethargy, muscle twitching, and ruffled coat as well as secretions from the eyes. All animals were normal three days following dosing through the 14-day observation period. No effect on body weight gain was observed.
Effects in Organs	No treatment-related gross abnormalities were observed at necropsy.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	Microbiological Associates Inc, USA (Microbiological 1989a)

7.4. Irritation – skin

TEST SUBSTANCE	Analogue A
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6 (3 male and 3 female)
Vehicle	Nil
Observation Period	7 days
Type of Dressing	Semi-occlusive
Remarks – Method	No protocol deviations from the OECD test method were reported. Compliance with GLP Standards was reported. Test sites were scored for dermal irritation for up to 7 days post patch application.

RESULTS

Remarks - Results	Six New Zealand white rabbits (3 male and 3 female) approximately 11 weeks of age weighing 2.4-2.5 kg and 2.5 kg respectively were chosen for the study. On the day before the test (day-1), the animals had the fur removed from the dorsal area of the trunk with care being taken to avoid abrading the skin during the clipping procedure. On the following day (day-0), each animal received 0.5 mL of the test substance as a single dermal application. The test substance was held in contact with the skin under a semi-occlusive binder for 4 h. Following the 4-h exposure period, the binder was removed and the test material removed from the skin using alcohol (first rinse) and mineral oil (second rinse). Each rinse was followed by soap, water and dry gauze. Test sites were examined for signs of erythema and oedema, and the responses scored according to the OECD TG 404, 1 hour after patch removal and 24, 48 and 72 hours, and up to 7 days after patch application.

Additional dermal findings of desquamation (scaling and flaking) were noted in three animals at 48 hour and in all six animals at the end of 7 days. Superficial lightening was noted in four animals at 24 hours, which resolved in three out of four animals at 48 hours, and in all animals at 72 hours. Transient incidences of dark material around the mouth were noted in three out of six animals during the study.

The individual dermal irritation scores at the end of 24, 48 and 72 hours are presented in the following table. The individual dermal irritation scores at the end of 1 h are not included in the table.

Table of Individual dermal irritation scores at 24, 48 and 72 hours after exposure

Animals	Erythema			Oedema		
	24 h	48 h	72 h	24 h	48 h	72 h
1	2	2	2	0	0	0
2	2	2	2	1	0	0
3	2	2	2	2	0	0
4	2	2	2	2	2	1
5	2	2	1	2	0	0
6	2	2	2	2	0	1

Following the grading of erythema and oedema for individual animals at the end of 24, 48 and 72 hours, the mean scores of individual and all animals for erythema and oedema at the end of 72 hours were determined. These are presented in the following table.

Mean scores of individual, and all animals for erythema and oedema at the end of 72 hours

Clinical findings	Mean scores of individual animals*						Mean scores of all animals**
	1	2	3	4	5	6	
Erythema	2	2	2	2	1.7	2	1.95
Oedema	0	0.3	0.7	1.7	0.7	1	0.73

*based on scores for each animal at the end of 72 h according to the Draize scoring method. **after 72 hours for all animals.

The mean scores of all animals were 1.95 for erythema, and 0.73 for oedema.

CONCLUSION — The notified polymer is irritating to the skin and classifiable under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

TEST FACILITY — Springborn Laboratories (2001a)

7.5. Irritation – eye

TEST SUBSTANCE — Analogue A

METHOD

Species/Strain	Rabbit/New Zealand White
Number of Animals	6 (3 male and 3 female)
Observation Period	14 days
Remarks - Method	No protocol deviations from the OECD test method were reported. Compliance with GLP Standards was reported. Three animals were scored for eye irritation for up to 72 hours, two animals were scored for eye irritation for up to 7 days and one animal was scored for eye irritation for up to 14 days post instillation.

RESULTS

Remarks - Results

Six New Zealand white rabbits (3 male and 3 female) were chosen, with each animal receiving a detailed pre-test observation prior to dosing. On day 0 prior to dosing, both eyes of each animal selected for the test were examined macroscopically for ocular irritation. In addition, the corneal surface was examined using fluorescin sodium dye. Following an approximately 15 second exposure, the eyes were rinsed and the corneal surface examined for dye retention. Animals exhibiting ocular irritation or pre-existing corneal injury were not used in the test. One hour after the preliminary ocular examination, 0.1 mL of the test substance H6410 without solvent was instilled in the conjunctival sac of the right eye of each rabbit. Following instillation, the eyelids were held together for approximately one second in order to limit the test article loss. The contralateral eye of each animal remained untreated and served as a control.
Following application of the test substance, the test and control eyes were examined for signs of irritation at 1, 24, 48 and 72 h and up to 14 days, and the effects on the cornea, iris and conjunctiva noted. The results were graded according to the OECD Ocular Grading System (TG 405), and the data classified according to the NOHSC *Approved Criteria* (NOHSC, 2004). The ocular irritation scores for all animals are presented in the following table.

Ocular Irritation Scores according to the OECD Ocular Grading System

Animals	Corneal opacity	Iris	Conjunc. redness	Chemosis	Conjunc. discharge
1					
24 h	0	0	2	2	0
48 h	0	0	1	1	0
72 h	0	0	0	0	0
2					
24 h	0	0	1	1	0
48 h	0	0	0	0	0
72 h	0	0	0	0	0
3					
24 h	2	1	2	2	0
48 h	1	1	1	1	0
72 h	0	1	1	1	0
4					
24 h	0	0	1	1	0
48 h	0	0	1	1	0
72 h	0	0	0	0	0
5					
24 h	1	1	2	2	0

48 h	0	0	1	1	0
72 h	0	0	1	1	0
6					
24 h	0	0	2	1	0
48 h	0	0	1	1	0
72 h	0	0	1	1	0

Based on the results of the Ocular Grading System, the mean ocular irritation score at the end of 72 h for all animals for corneal opacity was (0.2), iris lesion (0.2), conjunctival redness (1.1) conjunctival oedema (0.9) and conjunctival discharge (0) was determined.

CONCLUSION — The notified polymer is slightly irritating to the eye but not classifiable under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

TEST FACILITY — Springborn Laboratories (2001b)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE — Analogue B

METHOD — Consistent with OECD TG 471 Bacterial Reverse Mutation Test.

Plate incorporation procedure	
Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100
Metabolic Activation System	Rat liver S9 fraction from animals pre-treated with Aroclor 1254
Concentration Range in Main Test	a) With metabolic activation: 100-10000 µg/plate b) Without metabolic activation: 100-6667 µg/plate
Vehicle	Tetrahydrofuran
Remarks - Method	

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	*Cytotoxicity in Preliminary Test**	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>6667	–	333	negative
Present				
Test 1	>6667	–	333	negative

* Based on 'moderately reduced' (quantitatively unspecified) TA100 background lawn.

Remarks - Results — No substantial increases in the number of revertant colonies were seen in any strain either in the presence or absence of metabolic activation.

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

TEST FACILITY — Microbiological Associates Inc, USA (Microbiological 1989b)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE — Analogue B

METHOD — Consistent with OECD TG 474 Mammalian Erythrocyte Micronucleus Test.

Species/Strain — Mice

Route of Administration	Intraperitoneal injection single dose
Remarks - Method	No significant protocol deviations. Notified polymer in corn oil at 363, 1815 and 3630 mg/kg bw was injected into male and female mice. High dose level was selected to represent 80% of LD_{50}. Bone marrow cells were collected 24, 48 and 72 hours after treatment.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5 per sex	0	24, 48 and 72
II (low dose)	5 per sex	363	24, 48 and 72
III (mid dose)	5 per sex	1815	24, 48 and 72
IV (high dose)	5 per sex	3630	24, 48 and 72
V (positive control, TEM)	5 per sex	0.25	24

TEM=triethylenemelamine

RESULTS

Remarks - Results	No change in the ratio of polychromatic erythrocytes to total erythrocytes was observed. The negative and positive controls fulfilled the requirements for determination of a valid test.
CONCLUSION	The notified polymer was not clastogenic under the conditions of this in vivo Micronucleus test under conditions of the test.
TEST FACILITY	Microbiological Associates Inc, USA (Microbiological 1989c)

7.16. Toxicity to reproduction – two generation study

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 416 Two Generation Reproduction Toxicity Test.
Species/Strain	
Route of Administration	Oral – gavage
Exposure Information	Exposure period – F0 generation: 10 weeks prior to mating Exposure period – F1 generation: 10 weeks post paratum day 22
Vehicle	Corn oil
Remarks – Method	No significant protocol deviations. Compliance with GLP Standards was reported. Study incorporates a 28-day oral dose range finding toxicity study in rats to confirm the dosage groups for the two-generational reproductive toxicity test (Springborn Laboratories 2004).

Generation[+]	*Group*	*Number and Sex of Animals*	*Dose mg/kg bw/day*
P/F1	1	56 (28M/28F)	0
P/F1	2	56 (28M/28F)	100
P/F1	3	56 (28M/28F)	300
P/F1	4	56 (28M/28F)	1000

[+] F1 selected rats to produce the F2 generation.

Based on the results of the range finding toxicity study in rats, dosage levels of 100, 300 and 1000 mg/kg bw/day were selected for the two-generational reproductive toxicity study as no toxicologically meaningful effects were noted during the study with respect to clinical observations, body weight, body weight changes, food consumption or gross necropsy.

RESULTS

Mortality and Time to Death

No animals died during the observation period or were prematurely killed due to treatment. One F0 male (300 mg/kg bw/day) died due to an intubation error (perforated oesophagus); two F0 deaths of a female

(100 mg/kg bw/day) and a male (1000 mg/kg bw/day) were incidental, i.e., occurred in only one animal per treatment group and did not follow a dose-related pattern. No mortality occurred among similarly treated F1 parental animals.

Effects on animals:

Once daily oral administration of the notified chemical at dosage levels up to 1000 mg/kg bw/day had no significant effect on P and F1 survival, growth, mating behaviour, fertility, gestation, parturition or lactation. No treatment related mortality or clinical signs of toxicity were noted in the P and F1 animals or their offspring at any dosage level tested. F1 and F2 pup viability and growth were unaffected by the treatment. In addition, there were toxicologically meaningful differences noted among the treated animals with respect to oestrus cycling, sperm parameters, copulation and fertility indices, precoital interval, gestation lengths, gross necropsy findings or the onset of sexual maturation in F1 rats as measured by vaginal opening in females and preputial separation in males. The histopathological evaluations did not reveal any treatment-related changes in the reproductive organs or other tissues examined microscopically. A summary of incidental effects is given below.

F0 body weight and body weight changes

A few statistically significant differences in mean weekly weight gain were noted in F0 males and females, however, these did not follow any pattern which would indicate a relationship to treatment.

Mean lactation body weight changes

Mean weight gains in the 300 mg/kg bw/day females was significantly lower than controls during lactation days 14-21, however, this difference was considered incidental as it did not follow a dose-related pattern and occurred during the normal period of lactation cessation (final week of lactation).

F0 reproductive indices

The fertility index of 75% in the 1000 mg/kg bw/day F0 females was lower but not statistically different compared to the fertility index of 96.4% in F0 control females. This difference was considered incidental since the fertility index of the 1000 mg/kg bw/day F1 females dosed from postpartum day 22 through to sexual maturation was 100%.

F0 gross necropsy observations

While a number of gross necropsy findings were noted in one female (100 mg/kg bw/day) and two males (300 and 1000 mg/kg bw/day), these findings were dissimilar in nature, of low incidence and randomly distributed among the groups. Three control F0 females, five 100 mg/kg bw/day F0 females, two 300 mg/kg bw/day F0 females and seven 1000 mg/kg bw/day F0 females had positive evidence of mating but failed to deliver and therefore were euthanised and necropsied at 25 days following presumed gestation day 0. These females were listed as euthanised post breeding day 25. Gross necropsy of these females revealed that all the females were non-gravid except for two control animals. One of these control females was gravid with a retained fetus and the other control female was gravid by positive ammonium sulfide staining. The findings in these females were not considered toxicologically meaningful since there were no treatment-related differences in the F0 fertility indices.

F0 organ weights

Mean absolute and relative epididymal weights, and mean absolute and relative testis weights (left, right and combined testis weights) were statistically higher in the 100 and 300 mg/kg bw/day males. These

differences were not considered toxicologically meaningful since similar changes were not observed at the 1000 mg/kg bw/day level.

F1 pup observations during lactation

Observation of the F1 pups during lactation days 0 to 21 did not reveal any findings attributable to the test substance. Individual pup observations were generally of low incidence and randomly distributed among the groups.

F1 pup gross necropsy observations

Gross necropsy of stillborn pups (i.e., pups found dead at the time of litter processing), dead pups (i.e., pups found dead following litter processing) and surviving pups (i.e., pups euthanised on lactation day 21) did not reveal any specific changes or patterns of findings, which would indicate treatment-related effect.

F1 parental survival and clinical observations

All F1 animals selected to produce the F2 generation survived to scheduled euthanasia with the exception of one control female which was found dead on day 56 of the F1 growth phase. Although a definitive cause of death was not established for this female, gross necropsy revealed mottled lungs and fluid in the thoracic cavity, suggesting that this death was probably the result of an intubation error. Clinical observations of the F1 animals during the growth phase did not reveal any findings indicative of test substance-induced toxicity. Some clinical signs were noted; however, these tended to be of low incidence and randomly distributed among the groups. Moreover, those clinical signs which were observed did not follow any pattern which would indicate a relationship to test article treatment.

F1 parental body weights and body weight changes

A few statistically significant differences in mean weekly weight gain were noted, however, these did not follow any pattern which would indicate a relationship to treatment.

F1 parental food consumption

Several statistically significant food consumption values were observed in the 300 and 1000 mg/kg bw/day males (significantly higher than controls), however, these differences were generally small and did not follow any pattern which would indicate a relationship to treatment.

F1 parental gross necropsy observations

Gross necropsy findings for the single F1 control female found dead on day 56 consisted of a right pitted kidney on the cortical surface, mottled lungs, a fluid filled thoracic cavity and a trachea containing clear colorless fluid the entire length. Although the exact cause of death could not be determined for this female, the presence of mottled lungs and fluid in the thoracic cavity and trachea suggested that the death was probably the result of an intubation error.

Gross necropsy findings in the remaining surviving F1 parental rats were generally unremarkable. While a number of gross findings were noted, these tended to be dissimilar in nature, of low incidence, and randomly distributed among the treatment groups. One female each in the control, 300 and 1000 mg/kg bw/day groups had positive evidence of mating, but failed to deliver and therefore was euthanised and necropsied at 25 days following presumed gestation day 0 (these females were listed as euthanised post breeding day 25). Gross necropsy of these females revealed that all the females were nongravid by negative ammonium sulfide staining, except for the 1000 mg/kg bw/day female that was found to be gravid by positive ammonium sulfide staining and a uterus that contained two early resorptions. These findings were not considered toxicologically meaningful

since there were no treatment-related differences in the F1 fertility indices.

Two control females, two 100 mg/kg bw/day females, four 300 mg/kg bw/day females and two 1000 mg/kg bw/day females had no positive evidence of mating during the breeding period and therefore were euthanised and necropsied at 25 days following conclusion of the breeding period (these females listed as euthanised post breeding period day 25). Gross necropsy of these females revealed that all the females were found to be nongravid by negative ammonium sulfide staining, except for one 1000 mg/kg bw/day female that was found to be gravid by positive ammonium sulfide staining and a uterus that contained one early resorption. The findings in these females were not considered toxicologically meaningful since there were no treatment-related differences in the F1 fertility indices.

F2 pup gross necropsy observations

Gross necropsy of stillborn pups (i.e., pups found dead at the time of litter processing), dead pups (i.e., pups found dead following litter processing) and surviving pups (i.e., pups euthanised on lactation day 21) did not reveal any specific changes or patterns of findings which would indicate a test substance related effect. While a number of gross findings were noted, these tended to be dissimilar in nature, of low incidence, and randomly distributed among the groups.

F2 pup organ weights

Absolute and relative spleen weight of 300 mg/kg bw/day females, and relative spleen weight of 300 mg/kg bw/day males plus females (sexes combined), was statistically lower than the respective control values. These differences were considered incidental and unrelated to treatment since no such changes were observed at the 1000 mg/kg bw/day level.

Remarks – Results

There was no effect of the notified polymer on the integrity and performance of the reproductive system in male and female rats, including gonadal function, oestrous cycling, mating behaviour, conception, gestation, parturition, lactation, weaning, growth and development of the offspring.

CONCLUSION

A dosage level of 1000 mg/kg bw/day was considered the no-observed-adverse-effect level (NOAEL) for oral administration of notified polymer over two generations in rats.

TEST FACILITY Springborn Laboratories 2004

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted

8.1.2. Bioaccumulation

No bioaccumulation data were provided. Given the expected lack of release to the aquatic environment the notified polymer is not expected to bioaccumulate.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer will be imported pre-blended in a fuel additive package which will be blended with petrol locally. Therefore most of the notified polymer will be burned in the engine along with the fuel. No release to the environment is expected during blending and use except in the case of accidental spills.

The notified polymer having will exhibit surfactant properties, and as such is expected to reside at the interfaces between water and oil/organic matter. Spills occurring on land would be expected to be immobile and to remain in the surface soil layer, while spills occurring on water are expected to float on the surface.

Up to 10 tonne per year of the notified polymer could remain in the import containers after emptying. The majority of this residue (~80%) will be in isotainers which will be returned to the supplier for reuse. Import drums and any residual product are to be sent to a reconditioning facility where the drums will be rinsed and the residues sent to an onsite treatment plant. The notified polymer is expected to partition to the sludge and be removed prior to disposal to landfill.

It has been estimated that less than 100 kg annually of the notified polymer may be spilt at service stations during the filling of vehicles with fuel. These spills would be distributed across a maximum of 1500 service stations across Australia which it is estimated may be selling fuel containing the notified polymer. It is anticipated that spills of fuel containing the notified polymer will be typically confined to the concourse surfaces of the service station.

The notified polymer will be present in fuels at low levels. Incineration and combustion in engines will produce mainly water vapour and oxides of carbon and nitrogen.

9.1.2. Environment – effects assessment

No data were provided for the notified polymer. Under the reported use pattern, the notified polymer is not expected to enter the aquatic environment and to pose a hazard to aquatic organisms.

9.1.3. Environment – risk characterisation

Limited environmental release of the notified polymer is anticipated except in the case of accidental spills. The majority of the notified polymer will be burnt in engines along with the fuel. Any material lost as a result of spills, or remaining as residues in containers, is expected to be recovered and disposed of by incineration.

It is expected that fuel formulators are aware of the Fuel Quality Standards Act 2000 and Fuel Quality Standards Regulations 2001 which provides a legislative framework for setting national fuel quality and fuel quality information standards for Australia.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

As the notified polymer is not volatile, spills and splashes resulting in dermal and/or ocular contact are the most likely exposure scenario. Due to the molecular weight, the notified polymer is not expected to cross biological membranes. The low expected vapour pressure of the notified polymer precludes significant inhalation exposure.

Exposure to significant amounts of the notified polymer (60-100% notified polymer) is expected to be limited because of the engineering controls and personal protective equipment worn by workers during the characteristic occupational scenarios. These scenarios are described below.

Import, transport and distribution

During import, transport and distribution, workers are unlikely to be exposed to the notified

polymer except when packaging of the imported product (60-100% notified polymer) is accidentally breached or blended fuel (<1% notified polymer) is unintentionally released.

Dermal and accidental ocular exposure can occur during the transfer of blended fuel to service station storage tanks. However, exposure is expected be limited by the low concentration of notified polymer in the blended fuel and the use of dedicated transfer hoses.

Fuel blending
Dermal and ocular exposure can occur during certain fuel blending processes e.g. connection/disconnection of transfer hoses. However, exposure to significant amounts of the notified polymer (60-100% notified polymer) is expected to be limited due to engineering controls such as dedicated and enclosed fuel blending systems and by personal protective equipment worn by workers.

Exposure may occur during the transfer operations from storage/transport containers to blending units (60-100% notified polymer) and via the finished blended fuel (<1% notified polymer). Exposure via the blended fuel is expected be limited by the low concentration of notified polymer in the fuel, the use of dedicated transfer hoses and enclosed systems and the use of PPE.

Fuel users
Exposure of transport drivers and service station personnel to drips and spills may occur during the connection and disconnection of transfer hoses and during the filling of automobile fuel tanks. Exposure is expected to be negligible due to the transfer hoses used and the low concentration of notified polymer in the blended fuel. Fuelling of vehicles usually occurs in the open air and without the use of protective clothing. However, exposure occurs for a period of only a few minutes and the concentration of the notified polymer in the fuel is low.

The extent of potential dermal or accidental ocular exposure during the servicing of fuel systems is likely to be highly variable but limited by the low concentration of the notified polymer in the fuel.

9.2.2. Public health – exposure assessment

The notified polymer will be available to the public only after it has been blended with fuel at the refinery. Incidental dermal and accidental ocular exposure could occur during filling of the automobile fuel tank. The amounts to which the public will be exposed by means of fuel will be highly variable. Given the low concentration and the minimal direct contact with fuel under normal circumstances, public exposure is expected to be minimal.

Accidental ingestion of the notified polymer in fuel cannot be discounted. This could occur when syphoning petrol. Australian National Hospital Morbidity Data show approximately 133 hospital discharges/year between 1998 and 2000 were associated with the toxic effects of petroleum products (AIHW, 2002). Although no data were available on the amounts of fuel accidentally ingested, it is likely that only small amounts of fuel would be so ingested. Data collected by Watson et al. (1983) show that the average volume of a swallow (of tap water) for a child up to 5 years of age is between approximately 1 and 7 mL and for a person between 5 and 18 years of age is between 2 and about 30 mL. Given the low concentrations of the notified polymer in fuel, ingestion would involve potentially only very small amounts of the notified polymer and with the solvent nature of petroleum products, repeated ingestion or ingestion of larger amounts e.g. 100 mL or more is unlikely.

As a worst-case scenario, ingestion exposure is possible when orally siphoning petrol containing the notified polymer or from accidental ingestion by young children if petrol is stored inappropriately in or around the home. As a worst-case scenario, a child (10 kg) ingesting one mL of a fuel containing up to 1% notified polymer would receive no more than 10 mg (1 mg/kg bw) of notified polymer. This dose is many orders of magnitude lower than the oral LD50 for the notified polymer of >5 g/kg bw.

Exposure to the public by means of tail pipe emissions is unlikely as the notified polymer is combusted in the vehicle engine to oxides of carbon, nitrogen and hydrogen.

9.2.3. Human health – effects assessment

Based on the studies provided for the notified polymer and its analogues, the notified polymer is of low acute oral toxicity, not mutagenic or cytogenetic and is slightly irritating to eye. By analogy and based on dermal findings in rats of scaling and flaking up to 7 days post treatment, the notified polymer is irritating to skin. Based on an oral NOAEL of 1000 mg/kg bw/day in a two generation reproductive toxicity study, the notified polymer does not meet the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004) for classification as a substance toxic to reproduction, development or lactation.

The notifier advises that the notified polymer be regarded as irritating to the eye.

Based on the available data, the notified polymer is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Import, transport and distribution

The risk of adverse health effects as a result of dermal or ocular exposure to 60-100% notified polymer is predicted to be negligible except in the case of an accidental breach of the imported product's packaging.

Fuel blending

The risk of adverse health effects as a result of dermal or ocular exposure to 60-100% notified polymer is predicted to be low during the blending of fuel because of the fully enclosed and automated process used and the use by worker of PPE such as chemical resistant gloves, boots, chemical goggles or face shields, and long sleeves.

The product containing the notified polymer, E7844, is a hazardous substance according to the criteria of NOHSC, and due to constituents other than the notified polymer may cause lung damage if swallowed. During transport of this product, and the blending of the fuel, controls exist to limit occupational exposure to the hazardous substances. The use of local exhaust ventilation is recommended to control mist and vapours and to maintain the concentration of other ingredients below exposure levels. Exposure is further reduced by the use of personal protective equipment including chemical resistant gloves, boots, chemical goggles or face shields, and long sleeves.

Fuel use

As exposure is expected to be minimal during vehicle fueling operations and engine maintenance activities, there is a low risk in workers as a result of dermal or ocular exposure to the notified polymer because the notified polymer itself is not expected to be a skin or eye irritant at concentrations present in fuel.

Therefore, it can be concluded that there is a low occupational health and safety risk as a results of dermal and ocular exposure to the notified polymer under the conditions of the occupational settings described.

9.2.5. Public health – risk characterisation

The notified polymer itself is not sold to the public. Direct public exposure to the notified polymer may potentially occur primarily via the dermal and ocular route as a result of accidental spills and splashes of blended fuel containing the notified polymer. The notified polymer itself is not expected to be a skin or eye irritant at concentrations present in fuel and has low oral and dermal toxicity. Therefore, it can be concluded that there is a low risk in the general public as a result of dermal and ocular exposure or accidental oral exposure to the notified polymer in fuel.

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

10.1. Hazard classification

Based on the available data the notified polymer is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R38: Irritating to skin

As a comparison only, the classification of notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Skin corrosion/ irritation	2 Irritant	Causes skin irritation

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is No Significant Concern to public health when used as a fuel additive.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer as introduced containing the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

Based on the advice of the notifier that the notified polymer be regarded as both R36 Irritating to Eyes and R38 Irritating to Skin, the following risk phrase for products/mixtures containing the notified polymer are as follows:

– concentration $\geq$ 20%: R38 Irritating to skin

– concentration ≥ 20%: R36 Irritating to eyes

Use the following risk and safety phrases for products/mixtures containing the notified polymer:

– R36/38 Irritating to skin
– S 24/25 Avoid contact with skin and eyes
– S37/S39 Wear suitable gloves and eye/face protection

Suppliers should label the notified polymer with the signal word ‘Hazardous’ and the risk phrases listed above.

11.2. Label

The label for the notified polymer as introduced provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
HAZARD CLASSIFICATION AND LABELLING

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R38 Irritating to skin

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 20%: R38 Irritating to skin

CONTROL MEASURES
Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced in the product E7844:
  - Chemical-resistant gloves, chemical goggle or face shields, and long sleeves.

  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 incineration.

Emergency procedures

Spills/release of the notified polymer should be soaked up with inert material and placed in labelled containers for recycling or disposal by incineration

12.1. 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.

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