File No: STD/1110

18 May 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

TFA 4715

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

TFA 4715

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Oronite Australia Pty Ltd
Level 10, 45 William Street
MELBOURNE VIC 3000
ABN: 16 101 548 716

NOTIFICATION CATEGORY
Standard: Polymer with NAMW <1000 (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical name, other names, CAS number, structure, molecular formula, molecular weight, spectral data, purity, identity and percent toxic/hazardous impurities, non-hazardous impurities, import volumes, manufacture process and manufacturing sites.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

Melting/boiling point, Hydrolysis as a function of pH, Adsorption/desorption, Dissociation constant, Particle size, Flammability limits, Autoignition temperature, Water solubility, Vapour pressure, Water/octanol partition coefficient, Acute inhalation study, Induction of germ cell damage test, Chromosome damage test, Repeated dose toxicity study, Daphnia acute immobilisation test, Algal growth inhibition study.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
None

NOTIFICATION IN OTHER COUNTRIES
In the US: PMN submitted in 1987

2. IDENTITY OF CHEMICAL

OTHER NAME
Ref. Number 6933-28-5

3. COMPOSITION

DEGREE OF PURITY
High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Oronite Australia will import the notified polymer into Australia as part of an additive package containing up to 75% notified polymer. The additive package will be sold either to the gasoline marketers who will blend the additive package into gasoline or to customers who will blend the additive with solvent and package it into 350-, 500- and 600-mL bottles for sale as aftermarket fuel tank treatments.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Volume of notified polymer imported would be 10-30 tonnes per annum over the next 5 years.

USE
The notified polymer will be used as a fuel additive.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Oronite Australia Pty Ltd
Level 8, 520 Collins Street
Melbourne, VIC 3000

The notified polymer will be sold to gasoline marketers such as Caltex, BP and ExxonMobil.

TRANSPORTATION AND PACKAGING
The notified polymer will be transported to Australia by ship in 200 L drums. Transport within Australia will be by road.

5.2. Operation description

The notified polymer will be imported as part of an additive package. In Australia, it will either be blended into gasoline at <300 ppm, or will be blended with a solvent and packaged in smaller containers for sale as an aftermarket fuel tank treatment product containing <40% notified polymer.

The operations that will take place in Australia are transport of fuel additive package containing the notified polymer, its storage, blending, packaging and end-use.

Blending of the fuel additive into gasoline is done automatically using computer controlled additive injection equipment, which injects the additive into a tank truck containing gasoline. The gasoline containing the notified polymer is then distributed to service stations and large fleets. It will be transferred from the tank truck to storage tanks at the service stations. The top of the tank truck is opened and the product is pumped into the tank through hard piping.

For the preparation of the aftermarket fuel tank treatment, the additive package is pumped into a blender either from the drum or storage tanks and the solvent is added. The final blend is then packaged into 350-, 500- and 600-mL bottles using automatic packaging equipment.

The packaged aftermarket gasoline treatment containing the notified polymer will be used at auto repair shops by skill trade professionals.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and storage	10-20	1-2 hours/day	80 days/year
Analysing additive package	1/site	0.2 hours/day	80 days/year
Unloading drums	1-2/site	0.5 hours/day	80 days/year
Distribution to service stations	10-20	0.5 hour/day	220 days/year

Exposure Details

Transport and Storage

The notified polymer will be imported in 200 L drums. Transport and storage workers are not expected to be exposed to the notified polymer during transport except in case of an accidental spill.

Gasoline containing the notified polymer will be distributed to the service stations by tank trucks. The aftermarket fuel tank treatments will be distributed to mass merchandising stores, such as auto part stores, in 350-, 500- and 600-mL bottles.

The main route of exposure for transport and storage workers will be dermal. These workers will wear overalls, safety boots and gloves when handling containers.

Unloading and blending into gasoline

For unloading of drums workers will connect a pump line to the drum. The additive package will be pumped into a storage tank or directly into an in-line blender. The transfer process will be carried out by one to two workers on site. During connection and disconnection of lines, incidental skin contact from splashes, drips and spills is possible.

Blending of the additive package into petrol occurs in-line and is computer controlled, thereby minimising the potential for occupational exposure. The majority of the blended petrol is transferred automatically to petrol tanker trucks.

Additive package and blended petrol will be sampled for laboratory analysis. Incidental skin contact from splashes, drips and spills may occur during sample collection and analysis.

The gasoline containing the notified polymer is then distributed to service stations and large fleets. It will be transferred from the tank truck to storage tanks at the service stations. The top of the tank truck is opened and the product is pumped into the tank through hard piping. Mechanics and service station personnel may be exposed to the very low concentration of notified polymer in the final fuel, during routine work procedures. The likely routes of exposure are dermal and inhalation, although accidental eye contact may also occur, particularly while mechanics are working under vehicles.

Blending aftermarket fuel tank treatment

For the preparation of the aftermarket fuel tank treatment, an additive package containing 46-75% of the notified polymer is shipped to customers who add solvent to it. The additive package is pumped into a blender either from the drum or storage tanks and the solvent is added. The final blend is then packaged into 350-, 500- and 600-mL bottles using automatic packaging equipment. Exposure to workers would be minimal as the process is fully automated.

The packaged aftermarket gasoline treatment containing the notified polymer will then be used at auto repair shops by skilled trade professionals. Consumers who add the gasoline treatment to fuel tanks of their cars and skilled trade professionals at auto repair shops could be exposed to the notified polymer from drips or runs left on the outside of the container after emptying into the fuel tank. Dermal and ocular exposure is the most likely route of exposure.

5.4. Release

RELEASE OF CHEMICAL AT SITE

No manufacturing of the notified substance will occur in Australia. Environmental release of the notified substance is unlikely during importation, storage and transportation. Accidental spills, leaks and catastrophic mechanical failure during a transport accident are the most likely reason for environmental release. Established engineering controls (eg. 200 L drum specifications) and

established emergency clean-up procedures will limit the impact on the environment of such incidents. The blended fuel will be transported by road tanker to service stations and large fleet customers.

Bulk Fuel

Blending is undertaken by automated procedures using computer-controlled additive injection equipment. Release during blending procedures is unlikely. Release of chemical from splashes and drips during pumping from drums and accidental spillage is possible; however, engineering and institutional controls and procedures are likely to minimise the potential for environmental release.

Residues remaining in imported drums (~0.1% of notified polymer) will be sent to drum reconditioning facilities for steam cleaning and recycling, with wastewater (estimated by the notifier to contain 10 kg/year) treated prior to disposal to sewer (estimated by the notifier to contain ~10% of the inflow concentration; 1 kg/year) for further treatment prior to environmental discharge of treated effluent or effluent reclamation and reuse.

Aftermarket Products

Release during blending procedures is unlikely, with accidental spillage being the most likely reason; however, engineering and institutional controls and procedures are likely to minimise the environmental impact. These will be sold at mass merchandising stores such as auto part stores.

RELEASE OF CHEMICAL FROM USE

Fuels containing the notified polymer will have a widespread and diffuse use pattern in Australia. In general, release from bulk storage tanks (eg. USTs) to the subsoil and groundwater environment surrounding these tanks may occur over time due to corrosion and leakage of tanks or rupture of pipes and fittings. USTs have been installed throughout Australia at terminals and refineries, fuel depots, service stations, and many private facilities and organisations have USTs for fuel storage. Not all USTs leak. However, many in Australia have leaked in the past requiring decommissioning and land remediation. The length of service of the tank is one of a number of factors increasing the risk of UST leakage. Other factors include the type of construction materials, presence of liners, fuel type, fittings/pipes and environmental conditions surrounding the UST. Major fuel suppliers generally have tank decommissioning and replacement programs and install leak detection equipment on their tanks to prevent leaks from occurring and to trigger pollution abatement procedures to minimise risks to the environment where leaks are detected.

Except in the cases of gross spillage of fuel containing the notified polymer, eg. leakage from USTs or aboveground spillages, very little release to the soil compartment is likely and apart from areas in the vicinity of such spills and leaks no accumulation of the notified substance is likely in soils.

Application of the aftermarket product to the fuel tanks of vehicles, etc, may potentially result in small spillages/drips mostly on pavements at service stations where it is used.

5.5. Disposal

The majority of the notified chemical will be destroyed during use within internal combustion engines. The notifier indicates that the notified polymer is completely consumed during combustion of gasoline in the engine (see also Section 8.1.3). Emptied imported drums will be sent to drum reconditioning facilities for cleaning and reuse, with wastewaters treated on-site and/or off-site within the sewerage system. Emptied aftermarket containers will be either recycled, incinerated and/or sent to landfill for disposal, and these will have a diffuse use and disposal pattern. The notifier estimates that ~80 kg/year may enter landfills.

5.6. Public exposure

Public exposure to the notified polymer is expected to be occasional, but widespread, as gasoline containing the notified polymer will be sold to the public. Public exposure will occur when refilling petrol tanks either in automobiles or as petrol supplies for other uses (for example, mowers and garden equipment), and when adding gasoline treatment to their cars. The most likely routes of exposure are by dermal, inhalation and possibly ocular.

Public exposure to the notified polymer during transport and storage is not likely except in the event of an accidental spill.

Exposure of general public to the notified polymer

	Number	*Exposure Duration*	*Exposure Frequency*
Pumping gasoline	>1000,000	10 minutes	52 days/year
Adding fuel tank treatments	>10,000	10 minutes	52 days/year

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Pale yellow liquid

Many of the physical and chemical properties have been estimated for TFA-4715b. This name represents an individual constituent of the notified polymer, which is chosen to be the representative of the lower molecular weight species present.

Melting Point/Freezing Point 275ºC

METHOD Modelled, MPBPWIN version 1.41 module of EPIWIN version 3.11
Remarks Estimate based on EPIWIN modelling data for TFA-4715b
TEST FACILITY Chevron Oronite, USA (year not stated).

Boiling Point 633ºC at 101.3 kPa

METHOD Modelled, MPBPWIN version 1.41 module of EPIWIN version 3.11
Remarks Estimate based on EPIWIN modelling data for TFA-4715b
TEST FACILITY Chevron Oronite, USA (Date not provided).

Density 983 kg/m^3

Remarks Method not provided
TEST FACILITY Chevron Oronite, USA (year not stated).

Vapour Pressure 3.07 x 10^{-18} kPa at 20ºC

METHOD Modelled, MPBPWIN version 1.41 module of EPIWIN version 3.11
Remarks Estimate based on EPIWIN modelling data for TFA-4715b
TEST FACILITY Chevron Oronite, USA (year not stated).

Water Solubility 1.12 x 10^{-7} g/L at 20ºC

METHOD Modelled, WATERNT version 1.01 module of EPIWIN version 3.11
Remarks Estimate based on EPIWIN modelling data for TFA-4715b
TEST FACILITY Chevron Oronite, USA (year not stated).

Hydrolysis as a Function of pH Not determined

Remarks Insoluble in water. No groups expected to hydrolyse readily are present.

Partition Coefficient (n-octanol/water) log Pow = 7.8

METHOD Modelled, KOWWIN Version 1.67
Remarks Estimate based on EPIWIN modelling data for TFA-4715b
TEST FACILITY Chevron Oronite, USA (year not stated).

Adsorption/Desorption log K_{oc} = 3.78

METHOD Estimate based on EPIWIN modelling data for TFA-4715b
Remarks Report not provided
TEST FACILITY Chevron Oronite, USA (year not stated).

Dissociation Constant Not determined.

Particle Size Not applicable. Liquid.

Flash Point 243°C.

METHOD Pensky-Marten Closed Cup
Remarks Report not provided
TEST FACILITY Chevron Oronite, USA (year not stated).

Flammability Limits Data not provided.

Remarks Expected to be a combustible liquid.

Autoignition Temperature Data not provided.

Explosive Properties Data not provided.

Remarks Not expected to be explosive based on structure.

Reactivity Data not provided

Remarks Expected to be stable under ambient conditions. Not expected to be highly reactive

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD_{50} >5000 mg/kg bw	Low toxicity
Rat, acute dermal LD_{50} >2000 mg/kg bw	Low toxicity
Rat, acute inhalation	Data not provided
Rabbit, skin irritation	Slightly irritating
Rabbit, eye irritation	Slightly irritating
Guinea pig, skin sensitisation	Evidence of sensitisation.
Rat, repeat dose oral toxicity – 28 days.	NOAEL= 300 mg/kg bw/day (subchronic oral toxicity) NOAEL= 1000 mg/kg bw/day (Neurotoxicity)
Genotoxicity – bacterial reverse mutation	Non mutagenic
Genotoxicity – in vitro mammalian chromosomal aberration test	Non genotoxic
Genotoxicity – in vivo mammalian erythrocyte micronucleus test	Non genotoxic
Developmental and reproductive effects	No effect on reproductive system

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified polymer

METHOD OECD TG 401 Acute Oral Toxicity.

Species/Strain Rat/Sprague Dawley
Vehicle None
Remarks - Method Single oral dose by gavage

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/male	5000	0
2	5/female	5000	0

LD_{50}	>5000 mg/kg bw
Signs of Toxicity	No clinical signs or visible lesions were observed in the animals
Effects in Organs	None
Remarks - Results	None

CONCLUSION The notified polymer is of low toxicity via the oral route.

TEST FACILITY Chrysalis (1997a)

7.2. Acute toxicity - dermal

TEST SUBSTANCE Notified polymer

METHOD OECD TG 402 Acute Dermal Toxicity.

Species/Strain	Rabbit/New Zealand White
Vehicle	None
Type of dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/male	2000	0
2	5/female	2000	0

LD_{50}	>2000 mg/kg bw
Signs of Toxicity - Local	Erythema and/or edema of the skin at the application site on Days 2-15.
Signs of Toxicity - Systemic	None
Effects in Organs	None
Remarks - Results	Under the conditions of study, the dermal LD50 for the notified polymer was determined to be greater than 2000 mg/kg body weight.

CONCLUSION The notified polymer is of low toxicity via the dermal route.

TEST FACILITY Chrysalis (1997b)

7.3. Acute toxicity - inhalation

Data not provided. Variation of Schedule Requirements (acute inhalation toxicity) was requested by the notifier. TFA 4715 is not expected to be an inhalation hazard based on its low vapour pressure. In addition, the high viscosity makes it unlikely that aerosols of inhalable size would be generated under normal use conditions.

7.4. Irritation – skin

TEST SUBSTANCE Notified polymer

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	6

Vehicle	None
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	Animals were exposed to the chemical for 3 min, 1 hour or 4 hours.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	1	2	9 days	0
Oedema	<1	1	48 hours	0

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

Remarks - Results	The above results are from 4-hour exposure. Slight erythema occurred in treated skin areas of the 6 rabbits for up to 9 days. No symptoms of systemic toxicity were observed and no mortality occurred.

CONCLUSION The notified polymer is slightly irritating to skin.

TEST FACILITY Chrysalis (1997c)

7.5. Irritation - eye

TEST SUBSTANCE Notified polymer

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males and 3 females
Observation Period	5 days
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	1	1	72	0
Conjunctiva: chemosis	1.5	2	72	0
Conjunctiva: discharge	0	3	-	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	0	-	0

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

Remarks - Results	Only the conjunctivae were affected by the test substance. Corneal injury or iridial inflammation were not observed. The effects on conjunctivae had resolved within 72 hours in all animals. All scores were normal on Day 5.

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY Chrysalis (1997d).

7.6. Skin sensitisation

TEST SUBSTANCE Notified polymer

METHOD	OECD TG 406 Skin Sensitisation – Buehler Test.
Species/Strain	Guinea pig/Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 35%
MAIN STUDY	
Number of Animals	Test Group: 25 Control Group: 10
INDUCTION PHASE	Induction Concentration: topical: 100%
Signs of Irritation	Slight to moderate patchy erythema in 12 of the 20 test animals
CHALLENGE PHASE	
1st challenge	topical: 45%
2nd challenge	topical: 45%
Remarks - Method	Slight deviation from protocol – Control group was not challenged a second time.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	45%	15/20	19/20	17/20	16/20
Control Group	45%	5/10	6/10	N/C	N/C

N/C – Not challenged

Remarks - Results

At 24 hours, the test substance (45%) caused a response of 1 in 5 of 10 control animals at 24 hours. The test group induced with the test substance exhibited a score of zero in 5 of 20 animals, a score of ± (slightly patchy erythema) in 1 of 20 animals, a score of 1 in 6 of 20 animals and a score of 2 in 8 of 20 animals. Thus 9 of 20 test animals exhibited a score higher than the highest score in the control animals.

There were no signs of systemic toxicity during the study. No skin irritation was observed in animals induced and challenged with pure or 45% test substance.

The test however cannot be considered to be completely conclusive, as the concentration of the test substance chosen (45%) was above the maximum non-irritating concentration (35%).

CONCLUSION There was evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

TEST FACILITY Chrysalis (1997e).

7.7. Repeat dose toxicity

TEST SUBSTANCE SP 2043 (OGA 499, notified separately as NA/730)

METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rats/Crl:CD (SD)IGS BR
Route of Administration	Oral – gavage.
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 11 weeks
Vehicle	Corn oil
Remarks - Method	This is a combined 4-week repeated dose oral toxicity, reproduction and neurotoxicity study in rats. Thr reproduction phase is discussed

separately The test substance (SP 2043) is an analogue of the notified polymer. Based on the similarities in chemical structure and physico-chemical properties of the two analogues, toxicity data for SP 2043 was considered acceptable for toxicity assessment of the notified polymer.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5 males, 5 females	0	0/10
II (low dose)	5 males, 5 females	100	0/10
III (mid dose)	5 males, 5 females	300	0/10
IV (high dose)	5 males, 5 females	1000	0/10
V (control recovery)	5 males, 5 females	0	0/10
VI (high dose recovery)	5 males, 5 females	0	0/10

Mortality and Time to Death

There were no mortalities in either sex at any dose level. One control group female was found dead on Day 4.

Clinical Observations

Clinical findings, bodyweight gain, food consumption were comparable to the control group throughout the treatment and recovery periods. Increased incidence of yellow matting on the anogenital and urogenital areas, dried red material around the nose and soft stool were noted for the 1000 mg/kg/day group males in the reproduction phase between study weeks 6 and 11.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Serum Chemistry:

Significant findings at 1000 mg/kg/day were increased mean globulin for males at the end of treatment (Week 4) and end of recovery (Week 6). Consequently, the Week 4 albumin/globulin ratio was reduced and the Week 6 total protein was increased. Increased mean aspartate aminotransferase (AST) and potassium in females at Week 4 were observed together with increased mean calcium at Week 6 in males.

Urinalysis:

No significant findings at Weeks 4 and 6.

Haematology:

Significantly increased neutrophil count (absolute and differential) and a decreased lymphocyte count (differential only) in males at 1000 mg/kg/day at Week 4 and/or Week 6. However, the total leucocyte count for this group at Week 4 was comparable to that in the control group.

An increased incidence of anisocytosis was found in all treated females, and males of the 300 and 1000 mg/kg/day groups at Week 4, and in all treated animals at Week 6; the changes were considered minimal by the study authors. No changes in erythrocyte indices were observed.

Effects in Organs

Significantly increased mean spleen weights (absolute and relative to final body and brain weights) were observed in the 1000 mg/kg/day group females at the Week 4 necropsy. At the Week 6 necropsy, mean spleen weights relative to final body and/or brain weights for the 300 and 1000 mg/kg/day group males were significantly increased relative to control group values.

Neurotoxicity Effetcs

Clinical observations:

No treatment related clinical findings. No remarkable differences in body weights or food consumption to that of controls.

Functional Observation Battery:

Home cage and Handling observations:

No remarkable differences were apparent between the control and treated groups.

Open field observations:

Significantly decreased mean time to first step for all treated female groups at the Week 4 evaluation.

Sensory observations:
Significantly increased number of males in the 300 mg/kg/day group with no reaction to the touch response test at the Week 2 evaluation, but not at the Week 4 evaluation or in animals of the 1 000 mg/kg/day group at any evaluation.

Neuromuscular observations:
Significantly increased hind leg grip strength mean for the 1 000 mg/kg/day group females at the Week 2 evaluation, but not at the Week 4 evaluation.

Physiological observations and motor activity:
No apparent effect on activity, catalepsy, body temperature or mean body weight between the control and treated groups.

Plasma cholinesterase:
Cholinesterase activity was comparable between the treated and the control group throughout the treatment and recovery periods.

Brain weight and dimensions:
No treatment related differences in mean brain weight or brain measurements.

Microscopy:
No remarkable neuropathological lesions in the control and 1000 mg/kg/day groups.

Remarks – Results
There were no adverse effects on survival of the animals in the sub-chronic toxicity and neurotoxicity. No test substance related changes in clinical chemistry or urine parameters were recorded during the subchronic toxicity phase. An increased incidence of anisocytosis was observed during the treatment and recovery phases in treated animals. However this finding occurred in the absence of other red blood cell changes.

No remarkable differences were found between the treated and control groups in the functional observational battery and motor activity evaluations. No treatment related neuropathological lesions were observed.

Where examined, there were no treatment related macroscopic or microscopic lesions and no test substance related effects on organ weight data in adult male and female rats.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) determined for subchronic oral toxicity was 300 mg/kg/day, based upon substantial body weight decrease and clinical observations for the 1000 mg/kg/day group males in the reproduction phase of the study. The NOAEL for neurotoxicity was 1000 mg/kg/day, based upon the absence of adverse neurotoxic effects at this dose level.

TEST FACILITY WIL Research Laboratories (1999).

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure/Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102, TA97, TA97a. *E. coli*: WP2uvrA.
Metabolic Activation System	Aroclor 1254-induced rat liver S9 fraction
Concentration Range in Main Test	a) With metabolic activation: 1.67-500 µg/plate. b) Without metabolic activation: 1.67-500 µg/plate.
Vehicle	The notified polymer (clear colourless liquid) was diluted with DMSO.

Remarks - Method	The notified polymer was initially evaluated in strains TA1535 and TA1537 at doses of 1.67, 5.00, 16.7 and 500 µg/plate with and without S9 under liquid pre-incubation conditions, and at doses of 5.00, 16.7, 50.0, 167, 500 and 1670 µg/plate with and without S9 under plate incorporation conditions. The notified polymer was also evaluated in strains TA98, TA100, TA102 and WP2uvrA at doses of 50.0, 167, 500, 1670, 5000 and 10,000 µg/plate with and without S9 under both treatment conditions. It subsequently was re-evaluated under identical conditions in strain TA1537 with S9 under liquid pre-incubation conditions.

RESULTS

Remarks - Results	Inhibited growth (characterised by the absence of a confluent bacterial lawn and/or the presence of pindot colonies) was observed in strain TA1537 at doses ≥167 µg/plate under liquid pre-incubation condition and at doses ≥500 µg/plate under plate incorporation conditions and in strain TA100 at a dose ≥5000 µg/plate under liquid pre-incubation condition. No cytotoxicity was observed at any dose level, neither in liquid pre-incubation nor in plate incorporation conditions. Revertant frequencies for all doses of the notified polymer in all tester strains with and without S9, under plate incorporation conditions, approximated or were less than those observed in the concurrent negative control cultures. Positive and negative control values in both assays were within acceptable ranges.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Pharmakon USA (1997).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	SP 2043 (OGA 499, notified separately as NA/730)
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test. EC Directive 88/302/EEC B.18 DNA Damage and Repair – Unscheduled
Cell Type/Cell Line	Chinese hamster lung (CHL) cells
Metabolic Activation System	Liver fraction (S9 mix) from rats pre-treated with Aroclor 1254
Vehicle	McCoy's 5a culture medium
Remarks - Method	The aberration assays were conducted with a 24 hour harvest time in the initial assay and with 24 and 48 hour harvest times in the confirmatory assay. Chromosomal aberrations were analysed from the cultures treated at three dose levels, the solvent control and from one of the positive control doses.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period (hrs)*	*Harvest Time (hrs)*
Absent			
Test 1	0*, 100, 200, 400, 600*, 800, 1000*, 1200, 1600	6	24
Test 2	0*, 12.5, 25, 50*, 100*, 200*, 400, 600*, 800, 1000, 1200, 1600	24 or 48	24 or 48
Present			
Test 1	0*, 0.31, 0.62, 1.24, 314*, 626*, 1250*, 2500, 5000	6	24
Test 2	0*, 200, 400, 600, 800, 1000*, 1200, 1600*, 2000*, 2500	6	48

*Cultures selected for metaphase analysis.

RESULTS

Remarks - Results

Test 1 (Initial trial)

In both assays, with metabolic activation and without metabolic activation, no visual signs of toxicity were observed in one culture (replicate) at each dose level, however other replicate cultures at the respective doses had very unhealthy cell monolayers, reduction in the cell monolayer confluence, floating dead cells and debris, and slight reductions in the number of visible mitotic cells. This indicated that, although not visible, there was a precipitate present at these concentrations inducing differential toxicity depending on its dispersion in the culture medium.

Chromosomal aberrations were analysed from the cultures dosed with 600, 800 and 1000 μg/mL SP 2043 in the assay without metabolic activation and 314, 626 and 1250 μg/mL SP 2043 in the assay with metabolic activation. No statistically significant increases in cells with chromosomal aberrations, polyploidy or endoreduplications were observed at the concentrations observed.

Test 2 (Confirmatory Trial)

Observations similar to those in Test 1 were made in the confirmatory trial, both with and without metabolic activation. No statistically significant increases in cells with chromosomal aberrations, polyploidy or endoreduplications were observed at the concentrations observed.

The sensitivity of the cell culture for induction of chromosomal aberrations was shown by the increased frequency of aberrations in the cells exposed to mitomycin C, the positive control agent. The successful activation by the metabolic system was illustrated the increased incidence of cells with chromosomal aberrations in the cultures induced with cyclophosphamide.

CONCLUSION The test substance was not clastogenic to Chinese hamster lung cells treated in vitro under the conditions of the test.

TEST FACILITY Covance Laboratories Inc. (1999)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE SP 2043 (OGA 499, notified separately as NA/730)

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC B.12 Mutagenicity Mammalian Erythrocyte Micronucleus Test.

Species/Strain Mouse/Albino Crl:CD-1 (ICR) BR

Route of Administration Intraperitoneal

Vehicle Dried arachis oil

Remarks - Method A range finding study was conducted to determine the suitable dose level and route of administration for the micronucleus test. There was no marked difference in test material toxicity between the sexes; therefore the main test was performed using only male mice. The study was conducted using the intraperitoneal route in groups of seven mice at the maximum recommended dose of 2000 mg/kg with 500 and 1000 mg/kg as the two lower dose levels.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I	7 males	2000	48
II	7 males	2000	24
III	7 males	1000	24
IV	7 males	500	24
V (Vehicle control)	7 males	0	48
VI (Vehicle control)	7 males	0	24
VII (Positive control)*	5 males	50	24

*CP=cyclophosphamide

RESULTS

Doses Producing Toxicity	Clinical signs, hunched posture, piloerection, red/brown staining around mouth and lethargy were observed in animals dosed with 1000 mg/kg or more of SP 2043.
Genotoxic Effects	There were no statistically significant increases in the frequency of micronucleated polychromatic erythrocytes (PCE) at any dose groups at any sampling time compared with the control group.
Remarks - Results	The positive control group induced significant increase in micronuclei indicating that the test system responded appropriately. The observation of clinical signs was taken to indicate that systemic absorption had occurred.

CONCLUSION The test material, SP 2043 was not clastogenic in this in vivo mouse micronucleus assay under the conditions of the test.

TEST FACILITY Safepharm Laboratories Limited (1998a)

7.11 Toxicity to reproduction – one generation study

TEST SUBSTANCE SP 2043 (OGA 499, notified separately as NA/730)

METHOD

Species/Strain	
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 11 weeks
Vehicle	Corn oil
Remarks – Method	This is a combined 4-week repeated dose oral toxicity, reproduction and neurotoxicity study in rats. The test substance (SP 2043) is an analogue of the notified polymer. Based on the similarities in chemical structure and physico-chemical properties of the two analogues, toxicity data for SP 2043 was considered acceptable for toxicity assessment of the notified polymer.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5 males, 5 females	0	0/10
II (low dose)	5 males, 5 females	100	0/10
III (mid dose)	5 males, 5 females	300	0/10
IV (high dose)	5 males, 5 females	1000	0/10
V (control recovery)	5 males, 5 females	0	0/10
VI (high dose recovery)	5 males, 5 females	0	0/10

Mortality and Time to Death

There were no mortalities in either sex at any dose level. One control group female was found dead on Day 4.

Effects on Parental (P) animals:

Reproductive performance:

Administration of test substance revealed no adverse effects in reproductive performance, or mating and fertility indices.

Gestation length and Lactation:

Differences between the treated groups and control were slight and were not statistically significant. No

adverse signs were noted in the control or treated females during parturition.

Clinical observations:
Males of the 1 000 mg/kg/day group had increased incidence of yellow matting on the anogenital and urogenital areas during study weeks 7 through 11; dried red material around the nose and soft stool, generally between weeks 6 and 11.

Body weights:
Males of the 1 000 mg/kg/day group had significantly decreased mean body weights (13.5% relative to the control group at week 10), body weight gains and cumulative body weight gains which was attributable to administration of the test substance.

Organ weights:
In males of the 1 000 mg/kg/day group, mean absolute epididymal weights and mean liver weights (absolute and relative to brain weight) were significantly decreased compared to controls. The decrease was attributed to the reduced final body weight observed for this group. Mean brain, spleen, kidney and testis weights for males of the 1 000 mg/kg/day group were significantly elevated relative to final body weight. The mean testis weight relative to final body weight in the 300 mg/kg/day group was also significantly increased when compared to the control. However, the mean absolute weights for these organs were comparable to their respective control group values, as were the relative testes-to-brain weight values. The differences in organ-to-final body weight ratios were not considered to be related to treatment.

Macroscopy:
One female of the control group had no evidence of mating and was non gravid. One female of the 1 000 mg/kg/day group failed to deliver a litter. This female was non gravid. One female of the 100 mg/kg/day group had total litter loss on lactation Day 1. All 3 females were internally normal.

Microscopy:
No treatment related lesions were observed. The frequency of lesions observed in the 1000 mg/kg/day group were similar to that observed for the control group, or the findings were noted for a limited number of animals.

Effects on 1st Filial Generation (F1)

Litter data and postnatal survival:
No adverse effects on live litter size, viability, sex ratios or body weights or general physical condition at any dose level.

Mortality:
The number of pups examined that were found dead or euthanised *in extremis* were 16, 16, 10 and 3 in the control, 100, 300 and 1 000 mg/kg/day groups, respectively. In the same respective groups, 0, 3, 3 and 0 pups were missing and presumed to have been cannibalised.

Pup necropsies:
No significant treatment related findings.

Lactation Day 4:
Malformations - bilateral anophthalmia was observed in one pup of the 100 mg/kg/day group, and one pup of the 300 mg/kg/day group had hydrocephaly.
Developmental variations - one pup of the 1 000 mg/kg/day group had a major blood vessel variation; two pups of the control group and one pup of the 100 mg/kg/day group had a haemorrhagic ring around the iris; two pups of the control group had undeveloped renal papillae.

Remarks - Results
Treatment related decreased mean body weight (13.5% relative to the control group at week 10), body weight gains and cumulative body weight gain were observed in males of the 1000 mg/kg/day group. These decreases were sustained from the second week of treatment until the end of the study. Female weekly, gestational and lactational body weight and body weight gain were unaffected by test substance administration.

No adverse effects on reproduction in F_0 generation or development in the F_1 generation were observed.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) determined reproductive toxicity was 1000 mg/kg/day, based upon the absence of adverse reproductive or developmental effects at this dose level.

TEST FACILITY WIL Research Laboratories (1999).

8. ENVIRONMENT

8.1. Environmental fate
All data provided are for an analogue polymer which has a similar but an even more hydrophobic structure (previously notified as NA/730).

8.1.1a. Ready biodegradability

TEST SUBSTANCE	SP 2043 (Analogue)
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test (Modified Sturm Test).
Inoculum	A mixed population of activated sewage sludge micro-organisms from the aeration stage of the Severn Trent Water Plc sewage treatment plant (UK), which predominantly treats domestic sewage.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved organic carbon (DOC; 0.45 μm filtered) was monitored in test solutions in order to calculate the inorganic carbon/total carbon ratio in the test media. One CO_2 absorber was analysed (in triplicate) using a TOC Analyser on days 0, 1, 2, 3, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 27, 28, and 29. The second absorber was analysed on days 0 and 29.
Remarks - Method	Activated sludge was triple rinsed by settlement and resuspension in culture medium (based on OECD guidelines) to remove excessive DOC. A subsample of the washed sludge was analysed for suspended solids (SS). Test solutions consisted of a control consisting of inoculated culture medium only, a standard material (sodium benzoate 17.1 mg/L or 10 mg C/L) in inoculum, test material (10 mg C/L) in inoculum, and test material plus sodium benzoate (20 mg C/L) to act as a toxicity control. Each test vessel was inoculated giving a final concentration of 30 mg SS/L. Test temperature 21°C (in darkness). 24 h prior to testing, the test vessels were filled with inoculum (42.5 mL) and culture medium (2400 mL) and aerated. On day 0 the test and standard material were added and the final volume brought to 3 L (in 5 L culture vessels) by addition of culture medium. Culture vessels were sealed and CO_2-free air was bubbled through the solution (40 L/min) and stirred continuously. CO_2 produced by degradation was collected in two 500 mL Dreschel bottles containing 350 mL of 0.05 M NaOH. The test material (43.5 g) was dispersed directly in inoculated culture medium at a test concentration of 14.5 mg/L.

RESULTS

	% degradation	
Day	*Test substance*	*Sodium Benzoate*
0	0	0
1	4	11
6	11	73
10	19	97
16	41	98
28	50	100
29*	56	102*

* Day 29 values corrected to include any carry-over of CO_2 detected in the second CO_2 analyser.

Remarks - Results	Sodium benzoate degraded 100% after 28 days, validating the suitability of the inoculum and test conditions. The total CO_2 evolution in the control vessels on day 28 of 25.4 mg/L, the variability between test vessels for CO_2 evolution of less than 20%, and the inorganic carbon (IC) content of the test material suspension in the mineral medium at the beginning of the test being less than 5% of the total carbon content, were all within acceptable OECD validation criteria. The test substance attained 50% degradation after 28 days and failed to meet the OECD 10-day window criterion (ie. <60% degradation within 28 days). The toxicity control achieved 81% degradation after 28 days thereby confirming that the test material was not inhibitory to the microbes used in the study at the exposure concentration.
CONCLUSION	The test substance exhibited a potential for biodegradation, however, it cannot be considered to be readily biodegradable according to the OECD criteria.
TEST FACILITY	SafePharm Laboratories (1998b)

8.1.1b. Ready biodegradability

TEST SUBSTANCE	CP2043 (Analogue)
METHOD	OECD TG 301C Ready Biodegradability Modified MITI Test.
Inoculum	Activated sewage sludge micro-organisms
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	BOD was measured daily. DOC was analysed by DOC Analyser monitored at day 28. Residual test substance was monitored at day 28 by HPLC.
Remarks - Method	Test solutions consisted of a control consisting of inoculated culture medium only (bottle 2), a standard material (aniline 100 mg/L, Bottle 1) in inoculum, test material (100 mg/L, Bottles 3-5) in inoculum, and test material plus deionised water (100 mg/L, Bottle 6). Test material was added directly to the test vessels.

RESULTS

Day	*% degradation*	
	Test substance (BOD Method)	*Aniline (BOD Method)*
7	0	63
14	0	69
21	0	66
28	0	67

Remarks - Results	Solution in Bottle 1 was cloudy. Solutions in Bottles 2-6 were colourless. No growth of sludge was observed in Bottles 3-5. Sludge growth was evident in Bottle 1. Based on BOD measurement, aniline degraded by 63% after 7 days, validating the suitability of the inoculum and test conditions. After 28 days, the pH of the test solution was 7.2 (Bottles 3-5) and 8.5 (Bottle 6) (acceptable). Based on BOD measurement, the test substance attained 0% degradation after 28 days. Residue analysis at day 28 indicated 2% degradation after 28 days. New peaks were detected on the HPLC chromatograms and the test author suggests that some of the test substance was transformed during the exposure period. HPLC analysis of a stored sample of the test substance indicated that it was stable for the duration of the test. The report indicated that degradability based on DOC was not calculated as the test substance was insoluble in water.

CONCLUSION The test substance is not readily biodegradable under the conditions of the Modified MITI Test.

TEST FACILITY Mitsubishi Chemical Safety Institute Ltd (1998a), Japan.

8.1.2. Bioaccumulation

TEST SUBSTANCE CP2043 (Analogue)

METHOD OECD TG 305C Bioconcentration: Flow-through Fish Test.

Species	Carp (*Cyprinus carpio*). Fat Content measured 3.7% (3.1-4.3%, n=4), length 9.3-11.3 cm; weight 20.70-36.64 g.
Exposure Period	Exposure: 4 weeks Depuration: 0 days
Auxiliary Solvent	Disperse medium: HCO-60* (polyoxyethylene hydrogenated castor oil; 0.1 μg/mL). Dispersing agent: dimethylformamide DMF (1 ppm v/v)
Concentration Range	
Nominal	0.01 mg/L
Actual	0.0108-0.0112 mg/L
Analytical Monitoring	^{14}C-radioanalysis by Liquid Scintillation Counting of radiolabelled test substance in test solutions and test fish.
Remarks - Method	Two sets of continuous flow-through diluter systems were used (turn over 4.5 times/day). Primary stock solution (10000 mg/L of test substance) was prepared by dissolving radiolabelled test material (^{14}C; 165 mg) in 16.5 mL DMF. Diluter stock solution was prepared by addition of 2 mL of primary stock solution to 200 mg of HCO-60 and millipore water to 1000 mL (test substance concentration 20 mg/L). Nominal concentrations of test substance, HCO-60 and DMF were 0.01 mg/L, 0.1 mg/L and 1 ppm, respectively. Fish were fed during the test. Water temperature: 25±2°C. Dissolved oxygen: >4 mg/L. 12-15 fish/45 L test aquaria.

RESULTS

Bioconcentration Factor (BCF)	Week 1: 0.0112 mg/L	Week 2: 0.0108 mg/L	Week 4: 0.0108 mg/L
Whole Fish 1	3	5	5
Whole Fish 2	3	14	5

Remarks - Results HPLC analysis of stored test substance indicated that it was stable during the period of the test.

CONCLUSION BCF (whole fish) values of 3-14 resulted after 28 days exposure to 0.0108-0.0112 mg/L. The test substance has a low potential to bioconcentrate in fish.

TEST FACILITY Mitsubishi Chemical Safety Institute Ltd (1999), Japan.

8.1.3. Combustion and Air Emissions

The notifier submitted a 100,000 km Vehicle Emission Test Report (Chevron Texaco Global Lubricant, 2003) using a fleet of 6 taxis. Test vehicles, fitted with new factory-fitted engines at the start of the test, were treated with the formulated product containing the notified polymer (TECHRON®) every 3000 miles for the duration of the 18-month test. The test examined emissions of hydrocarbons (HC), carbon monoxide (CO), nitrous oxides (NOx), carbon dioxide (CO_2) and non-methane hydrocarbons (NMHC), engine cleanliness (continuous use) and fuel economy (by carbon balance). A control vehicle was also tested. All vehicles were subjected to the same maintenance. Emissions were measured at the end of the test (no details provided on whether after cold start or warmed up engine), and fuel economy was calculated by carbon balance. Overall, the test report indicates similar or no worse effects on engine cleanliness (eg. valve deposit, valve intake and port carbonisation, cam shaft, rocker cover, fuel injector flow and cleanliness), emissions of the abovementioned parameters, fuel economy and oil consumption, with respect to the control. Only summary data in graphs and tables were provided. Emissions of all analytes tended to be lower, and CO emissions were apparently statistically significantly lower for vehicles using the finished product, indicative of better fuel combustion and economy.

In addition, the notifier provided a study report (Chevron Oronite Company, 2003) on the use of the formulated product containing the notified polymer (OGA 72012) at different rates of usage in several tests on intake valve and/or combustion chamber cleanliness (single use clean up and continuous use cleanliness). Engines tested included Honda generator, BMW, Mercedes Benz M102E, Ford 2.3 L, GM 3.1 L, Dodge Intrepid 3.3 L and Yamaha Y350 M2. Overall, the test report indicates similar or no worse effects on intake valve deposition, valve sticking, valve clean up or maintaining cleanliness, which can effect emissions and fuel economy.

8.2. Ecotoxicological investigations

8.2.1a. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer (Water-accommodated fraction; WAF)
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static.
Species	Fathead minnow (*Pimephales promelas*), 14 days pre-test acclimation, controls weighed 0.21 g (29.3 mm length) at end of test.
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	40 mg/L (as $CaCO_3$; soft water)
Analytical Monitoring	None
Remarks – Method	Two range finding and one definitive test was conducted. Test solutions were prepared by addition of various quantities of test substance in dilution water adjusted to 35 L. The mixture was stirred for 24 h at room temperature and allowed to settle for 4 h before the WAF was siphoned off for use. Tests were conducted in duplicate. Dilution water consisted of carbon filtered deionised water. Test conditions were acceptable (DO: ~7.8 mg/L, Temp: ~22±1°C, pH: 7.4-8.2, photoperiod 16 light: 8 h dark). LC50 values were calculated using the method of Stephan (1983).

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*% Survival*		*% Affected*	
		48 h	*96 h*	*48 h*	*96 h*
Control	10 (2 replicates)	100	100	0	0
60	"	100	100	0	0
100	"	100	100	0	0
170	"	100	100	0	0
280	"	100	100	0	0
460	"	100	100	0	0
770	"	0	0	100	100

LC50 600 mg/L WAF at 96 hour (95% CI 460-770 mg/L).

NOEC	460 mg/L WAF at 96 hours.
Remarks – Results	A thin film of undissolved material was observed on the surface of 280 and 460 mg/L WAF test containers throughout the test. The 780 mg/L WAF solution was cloudy from 0-48 h. 1-3 fish were affected (lethargic and lack of equilibrium) after 24 h at the highest test concentration. No analysis such as total organic carbon (TOC) of solutions was made.
CONCLUSION	The test substance is toxic to fish up to the limit of its water solubility but due to undissolved material, this may be a physical rather than chemical effect.
TEST FACILITY	T. R. Wilbury Laboratories, Inc (1997a)

8.2.1b. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer (Water-accommodated fraction; WAF)
METHOD	OECD TG 203 Fish, Acute Toxicity Test - flow through/saltwater.
Species	Sheepshead minnow (*Cyprinodon variegatus*), 14 days pre-test acclimation, controls weighed 0.28 g at end of test.
Exposure Period	96 h
Auxiliary Solvent	None
Salinity	16 parts per thousand (ppt)
Analytical Monitoring	None
Remarks – Method	Range-finding and definitive tests were conducted. Test solution (1000 mg/L nominal) was prepared by addition of test substance (30.0 g) in dilution water adjusted to 30 L. The mixture was stirred for 24 h at room temperature and allowed to settle for 4 h before the WAF was siphoned off for use. Two stock solutions were prepared and the WAF solutions were combined. Tests were conducted in replicate. Dilution water consisted of filtered seawater diluted to 16 ppt with deionised water. Test conditions were acceptable (DO: ~6.5 mg/L, Temp: ~22±1°C, pH: 7.5-8.6).

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*% Survival*		*% Affected*	
		48 h	*96 h*	*48 h*	*96 h*
Control	10 (3 replicates)	100	100	0	0
1000	"	100	100	0	0

LC50	>1000 mg/L WAF at 96 hours.
NOEC	1000 mg/L WAF at 96 hours (highest test concentration).
Remarks – Results	Cloudiness and a thin film of undissolved material were observed on the surface of all non-control aquaria throughout the test. All test organisms survived the 96 h exposure to the test substance (1000 mg/L WAF) and there were no sublethal effects observed.
CONCLUSION	The test substance not toxic at the limit of its seawater solubility.
TEST FACILITY	T. R. Wilbury Laboratories, Inc (1997b)

8.2.1c. Acute toxicity to fish

TEST SUBSTANCE	CP2043 (Analogue)
METHOD	Japanese Industrial Standard Method JIS K 0102-1986 Industrial waste water Testing Method 71 "Acute Toxicity Study using Fish" - Static
Species	Orange killifish (*Oryzias latipes*). Mean length 2 cm. Mean weight 0.2 g.
Exposure Period	48 h (preliminary test for bioaccumulation test, see Section 8.1.2)

Auxiliary Solvent	Dimethylformamide
Water Hardness	Not reported
Analytical Monitoring	None
Remarks – Method	The test was carried out as a preliminary range-finding test for the bioaccumulation test above. Stock solution (100000 µg/mL) was prepared by dissolving 1000 mg of non-labelled test substance in DMF and diluting to 10 mL (Solution I). 20 g of dispersing agent (HCO-60) was dissolved and diluted to 10 mL with deionised water (Solution II). Test solutions were prepared by addition of various volumes of Solutions I and II into dechlorinated water to a final volume of 3 L. Dissolved oxygen range: >6.2 mg/L. Test temp: 25±2°C. Test water pH not stated. Photoperiod not reported. Fish were not fed during the test. Test aquaria were continuously aerated during the test.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*	
Nominal	*Actual*		*48 h*	*96 h*
0*	Not determined	10 per aquaria	0	0
10	"	"	10	10
20	"	"	0	0
30	"	"	0	0
60	"	"	20	30
100	"	"	60	100

* The control contained Solution II and DMF (3.0 mL aliquot).

LC50	69 mg/L at 48 hours (nominal).
NOEC	30 mg/L at 48 hours (nominal).
Remarks – Results	No sublethal effects were monitored for or reported. It is not reported whether solutions were clear, or more likely, contained undissolved material.

CONCLUSION The test material was acutely harmful to the fish species tested under the conditions of the test (United Nations, 2003; LC50 of 10-100 mg/L). However, this result should be treated with caution as toxicity may have been caused through a physical effect due to the presence of undissolved material.

TEST FACILITY Mitsubishi Chemical Safety Institute Ltd (1999), Japan.

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer (Water-accommodated fraction; WAF)

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

Species	Cladoceran (*Daphnia magna*; <24 hour old)
Exposure Period	48 h
Auxiliary Solvent	None
Water Hardness	176 mg/L (as $CaCO_3$; hard water)
Analytical Monitoring	None
Remarks – Method	Range finding and definitive tests were conducted. Test solution (1000 mg/L nominal) was prepared by addition of test substance (1.0 g) in dilution water adjusted to 1 L. The mixture was stirred for 24 h at room temperature and allowed to settle for 4 h before the WAF was siphoned off for use. Tests were conducted in replicate. Dilution water consisted of deionised water. Test conditions were acceptable (DO: 8.0-8.7 mg/L, Temp: ~20±1°C, pH: <8.0, photoperiod 16 light: 8 h dark).

RESULTS

Concentration mg/L Nominal	*Number of Daphnids*	*% Survival*		*% Affected*	
		48 h	*96 h*	*48 h*	*96 h*
Control	10 (3 replicates)	100	100	0	0
1000	"	100	100	0	0

EC50	>1000 mg/L WAF at 48 hour
NOEC	1000 mg/L WAF at 48 h (highest concentration tested).
Remarks – Results	No insoluble material was observed during the test.
CONCLUSION	The test substance (analogue polymer WAF) is not toxic at the limit of its water solubility.
TEST FACILITY	T. R. Wilbury Laboratories, Inc (1997c)

8.2.3a. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer (Water-accommodated fraction; WAF)
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	Green algae *Selenastrum capricornutum* (freshwater unicellular)
Exposure Period	96 hours
Concentration Range	
Nominal	0 (control), 33, 65, 130, 250, 500 and 1000 mg/L WAF
Auxiliary Solvent	None
Water Hardness	Not stated
Analytical Monitoring	None
Remarks - Method	Range finding and definitive tests were conducted. Test solutions were prepared by addition of various quantities of test substance in dilution water adjusted to 35 L. The mixture was stirred for 24 h at room temperature and allowed to settle for 4 h before the WAF was siphoned off for use. Tests were conducted in replicate. Dilution water consisted of sterile synthetic media adjusted to pH 7.5 with 1 N HCl. Temp: ~24±1°C, photoperiod 24 light: 0 h dark, continuous rotation). ~10000 cell/mL were distributed into each replicate. Cell counts were made daily using a haemocytometer. EC50 values were calculated using the probit method of Stephan (1983) and the NOEC calculated using TOXSTAT Version 3.3 (Gulley et al., 1990), which calculated an ANOVA of the number of cells/mL and of the average specific growth rate in each test vessel at the end of the test. The data were tested for normality using a Shapiro-Wilks Test and for homogeneity of variance using a Bartlett's Test.

RESULTS

Biomass		*Growth*	
EbC50 mg/L WAF at 96 h	*NOEC mg/L WAF*	*ErC50 mg/L WAF at 96 h*	*NOEC mg/L WAF*
330	130	>1000	130

Remarks - Results	Water quality throughout the test was within acceptable limits. Insoluble test material was not observed in any of the test containers. Algae grew well during the tests, with ~10^7 cells/mL at the end of the test. No effects (size differences, unusual cell shapes, colours, flocculations, adherence of cells to test containers or aggregations of cells) were noted in the test.
CONCLUSION	The test substance showed some toxicity to algae at the limit of its water solubility.
TEST FACILITY	T. R. Wilbury Laboratories, Inc (1997d)

8.2.3b. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer (Water-accommodated fraction; WAF)
METHOD	OECD TG 201 Alga, Growth Inhibition Test and USEPA (1993).
Species	Marine Alga, *Skeletonema costatum*.
Exposure Period	96 hours
Concentration Range	
Nominal	0 (control), 25, 50, 100, 200 and 400 mg/L WAF
Auxiliary Solvent	None
Salinity	Not stated. The dilution water consisted of sterilised seawater. Chloride content 19600 mg/L.
Analytical Monitoring	None
Remarks - Method	Range finding (up to 1000 mg/L WAF) and definitive tests were conducted. Test solutions were prepared only at the beginning of the test by addition of various quantities of test substance in dilution water. The mixture was stirred for 24 h at room temperature and allowed to settle for 4 h before the WAF was siphoned off for use. Tests were conducted in replicate in 250 mL Erlenmeyer flasks containing 50 mL of test solution. Dilution water consisted of sterile marine water to pH 8.1-8.2 with 1 N HCl. Temp: 19.8-20.6°C. Photoperiod 16 light: 8 h dark with continuous rotation; 50 μEin/m^2sec). Test solution pH range: 8.2-8.5. Approximately 77000 cell/mL were distributed into each replicate. Cell counts were made daily by microscopic examination using a haemocytometer. EC50 values were calculated using the probit method of Stephan (1983) and the NOEC calculated using TOXSTAT Version 3.3 (Gulley et al., 1990), which calculated an ANOVA of the number of cells/mL and of the average specific growth rate in each test vessel at the end of the test. The data were tested for normality using a Shapiro-Wilks Test and for homogeneity of variance using a Bartlett's Test.

RESULTS

Biomass		*Growth*	
EbC50	*NOEC*	*ErC50*	*NOEC*
mg/L WAF at 96 h	*mg/L WAF*	*mg/L WAF at 96 h*	*mg/L WAF*
84	25	110	25

Remarks - Results	Nominal concentrations were used for all calculations. Water quality throughout the test was within acceptable limits. Insoluble test material was not observed in any of the test containers. Algae grew well during the tests, with ~10^7 cells/mL at the end of the test. No effects (size differences, unusual cell shapes, colours, flocculation, adherence of cells to test containers or aggregations of cells) were noted in the test. Follow up tests with the 400 mg/L WAF showed that the test substance was algistatic rather than algicidal.
CONCLUSION	The test substance showed some algistatic toxicity to marine algae at the limit of its water solubility.
TEST FACILITY	T. R. Wilbury Laboratories, Inc (1997e)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	SP 2043 (Analogue polymer)
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test, EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test and USEPA Draft Ecological Effects Test Guidelines OPPT 850.6800.
Inoculum	Mixed biological population from a secondary treated (activated) sludge, Severn Trent Water plc, UK., receiving mainly domestic sewage (pH 7.4; Suspended solids 3.9 g/L).
Exposure Period	3 hours
Concentration Range	
Nominal	1000 mg/L (nominal)
Remarks – Method	Range-finding (at 100 and 1000 mg/L) and definitive tests were performed. Test material was aerated for 3 h at 21°C in the presence of activated sewage sludge and synthetic sewage sludge. Test material (500 mg) was dispersed in 250 mL of water and subjected to ultrasonication (30 mins). Synthetic sewage sludge (16 mL), activated sewage sludge (200 mL) and water (activated carbon filtered; hardness 100 mg/L as $CaCO_3$) were added to a final volume of 500 mL to give the test material concentration of 1000 mg/L. Controls (300 mL) consisted of sewage sludge (16 mL), water and 200 mL inoculum. Two stock solutions of a reference material (3,5-dichlorophenol) were prepared (50 and 160 mg/L) by direct addition in water and ultrasonication. Aliquots (10 and 100 mL) of the stock solution were dispersed in activated sewage sludge, synthetic sewage sludge and water to give final concentrations of 3.2 and 32 mg/L. Similarly, a 100 mL aliquot of the 50 mg/L solution was used to prepare a 10 mg/L concentration. Tests were conducted in replicate. After 30 minutes contact time, an aliquot was removed from test containers and poured into a measuring vessel (250 mL darkened BOD bottle) and the rate of respiration was monitored with a DO meter. The rate of respiration was monitored over the linear portion of the oxygen consumption trace for ~10 minutes (between 8.0 mg O_2/L and 1.2 mg O_2/L). The procedure was repeated after 3 h.
RESULTS	
EC50	>1000 mg/L at 3 h
NOEC	1000 mg/L at 3 h (highest nominal test concentration)
Remarks – Results	The 30 h EC50 of the reference toxicant was 7.0 mg/L (within the acceptable range of 5-30 mg/L) and the control respiration rate was acceptable. At the test concentration of 1000 mg/L, respiration increased by 10% when compared to the control.
CONCLUSION	The test material did not inhibit the respiration of sewage sludge microbes up to a concentration of 1000 mg/L, which is well above the limit of water solubility. Duplicate test results of controls varied by only ±2% after 30 minutes.
TEST FACILITY	SafePharm Laboratories Ltd (1998c)

8.2.5. Summary of Ecotoxicity Data

The aquatic ecotoxicity data presented below mostly used WAF well above solubility limits and in some cases the WAF was cloudy and effects observed may have been physical rather than chemical.

Organism	Test Substance	L(E)C50	NOEC
Freshwater spp.			
Fathead minnow	Notified polymer; WAF	600 mg/L at 96 h	460 mg/L at 96 h
Orange killifish	Analogue (CP2043) WAF	69 mg/L at 48 h	30 mg/L at 48 h
Cladoceran*	Notified polymer; WAF	>1000 mg/L at 48 h	1000 mg/L at 48 h*
Freshwater Green algae	Notified polymer; WAF	330 mg/L at 96 h **	130 mg/L at 96 h
Sewage sludge microbes	Analogue polymer	>1000 mg/L at 3 h	1000 mg/L at 3 h*
Marine spp.			
Sheepshead minnow	Notified polymer; WAF	>1000 mg/L at 96 h	1000 mg/L at 96 h*
Marine alga	Notified polymer; WAF	84 mg/L at 96 h**	25 mg/L at 96 h*

* Highest nominal test conc. ** EbC50 (biomass).

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Release of the notified polymer to the environment is not expected. Estimated data for a representative species of the polymer indicates that with a vapour pressure of $3.07X10^{-18}$ kPa at 20°C, volatilisation of the notified polymer to the atmosphere is not expected. The low water solubility ($1.12X10^{-7}$ g/L at 20°C) indicates that dissolution and migration in runoff or percolation to groundwater is unlikely, and the absence of hydrolysable groups indicates aqueous stability. The adsorption co-efficient (log Koc of ~3.78) indicates an affinity to sediments, soils and organic matter. The octanol/water partition co-efficient (log Kow 7.8) indicates a high affinity to organic matter and lipids; however, bioaccumulation is expected to be low (28 d BCF 3-14) based on bioconcentration test results. No data are available on solubility in co-associated fuel, which may potentially act as a carrier agent in larger fuel spill/leak events. The notified substance is expected to degrade over time by biodegradation processes, as indicated by ready biodegradability testing.

9.1.2. Environment – effects assessment

Aquatic toxicity data were available for 4 taxonomic groups; fish (fresh and marine), invertebrates, algae (fresh and marine) and sewage sludge microbes. The notified polymer was generally not toxic up to the limit of water solubility and the lowest EC50 value for the notified polymer WAF was 84 mg/L to marine algae. A predicted no effect concentration (PNEC) was not estimated as several toxicity tests noted the presence of undissolved test material on the surface of the test solutions, and the results may be due to physical effects on biota. No analysis of WAF solutions was made to estimate the concentrations in the test solution WAFs. Secondary ecosystem effects (eg. dissolved oxygen reduction) cannot be discounted after significant releases to waters (eg. large spills).

9.1.3. Environment – risk characterisation

The majority of the notified polymer imported will be destroyed during combustion within internal combustion engines to release oxides of carbon and nitrogen, and summary results of engine tests indicate similar or improved fuel economy and emissions, particularly CO. The use and disposal pattern indicates a widespread and diffuse use pattern with very limited potential for the notified polymer to be released to the environment. Consequently, no predicted environmental concentration (PEC) has been determined. Within a landfill environment, the notified polymer is not expected to be mobile and will likely biodegrade over time to simpler compounds.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and Storage

The notified polymer will be imported in 200 L drums. Transport and storage workers are not expected to be exposed to the notified polymer during transport except in case of an accidental spill.

Gasoline, containing the notified polymer, will be distributed to service stations by tank trucks. Dermal exposure to drips and spills of blended gasoline is possible during the connection and disconnection of transfer hoses when filling the bulk tankers. The main route of exposure for transport and storage workers will be dermal. These workers will wear protective clothing, safety glasses, rubber gloves and a hard hat.

The notified polymer has a very low vapour pressure, minimising the possibility of vapour and aerosol formation. Worker exposure will be minimised by the use of gloves.

The aftermarket fuel tank treatment liquid will be distributed to mass merchandising stores in 350-, 500- and 600-mL bottles. Transport workers and storekeepers are not likely to be exposed to the notified polymer, unless packaging is breached.

Blending
Blending of the fuel additive into gasoline is done automatically using computer controlled additive injection equipment. Worker exposure is expected to be minimal.

For the preparation of the aftermarket fuel tank treatment, the additive package is pumped into a blender either from the drum or storage tanks and the solvent is added. The final blend is then packaged into 350-, 500- and 600-mL bottles using automatic packaging equipment. Exposure to workers would be minimal as the process is fully automated.

The packaged aftermarket gasoline treatment containing the notified polymer will be used at auto repair shops by skill trade professionals. Consumers who add the gasoline treatment to fuel tanks of their cars and skill trade professionals at auto repair shops could be exposed to the notified polymer from drips or runs left on the outside of the container after emptying into the fuel tank. Dermal and ocular exposure is the most likely route of exposure.

9.2.2. Public health – exposure assessment

Public exposure to the notified polymer is expected to be occasional, but widespread as gasoline containing the notified polymer will be sold to the public. Public exposure will occur when refilling petrol tanks either in automobiles or as petrol supplies for other uses, such as mowers and garden equipment. The most likely routes of exposure are dermal, inhalation and possibly ocular.

Public exposure to the notified polymer during transport and storage is not likely except in the event of an accidental spill.

9.2.3. Human health - effects assessment

The notified polymer was of very low acute oral toxicity (LD_{50}>5000 mg/kg) and low acute dermal toxicity (LD_{50}>2 000 mg/kg) in rats. It was a slight eye and skin irritant. Although no acute inhalation studies have been conducted, the notified polymer is not expected to be an inhalation hazard based upon its low vapour pressure.

The notified polymer showed evidence of skin sensitisation in guineapigs.

In a combined repeated oral dose study (sub-chronic toxicity, neurotoxicity and reproductive toxicity) rats received 0, 100, 300 or 1000 mg/kg/day of notified polymer. No treatment related findings were observed at any dose level in the subchronic or neurotoxicity phases. An increased incidence of yellow matting on the anogenital and urogenital areas, dried red material around the nose and soft stool were noted for males of the 1000 mg/kg/day group in the reproductive study, in addition to a significant decrease in bodyweight in this group. These findings were considered to be treatment related. The NOAEL determined for the subchronic oral toxicity was 300 mg/kg/day, based upon body weight effects and clinical observations for the 1000 mg/kg/day group males in the reproduction phase of the study. The NOAELs for neurotoxicity and reproductive toxicity were 1000 mg/kg/day based upon the absence of adverse neurotoxic, reproductive or developmental effects at this dose.

The notified polymer was not considered mutagenic in a bacterial reverse mutation assay. Genotoxicity was not observed in mammalian cells *in vivo* or *in vitro*.

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, 2002). The overall hazard classification for TFA 4715 is skin and eye irritant and skin sensitiser with risk phrases R36/38 – Irritating to Eyes and Skin and R43- May Cause Sensitisation by Skin Contact.

9.2.4. Occupational health and safety – risk characterisation

During importation and transport of additive packages containing the notified polymer 200 L

steel drums, there is unlikely to be any worker exposure except in the event of a spill. Exposure after a spill would need to be controlled by use of the recommended practices for spillage clean up given in the Material Safety Data Sheet supplied by the notifier. These workers will need to have access to protective clothing to minimise exposure.

The transfer and blending operations at the refinery/terminal facilities are enclosed and automatically operated. However, exposure to the additive package containing the notified polymer may occur during transfer operations, as delivery lines are connected/disconnected from the import containers, and during sampling for laboratory analysis. The process in which the notified polymer is used is considered non-dispersive and exposure incidental. Inhalation will be a minor route of exposure given the low vapour pressure. Potential for slight, transient eye irritation may occur following eye contact. Skin contact is expected to be the major route of exposure; the health effect of concern by this route is skin sensitisation. Although the risk of skin sensitisation from notified polymer is expected to diminish with the final blended petrol containing less than 0.1% notified polymer.

Because of the hazardous nature of fuel and fuel products encountered at refineries and terminals, standard operating procedures at these sites require workers to wear appropriate personal protective equipment to control exposure to these substances in order to minimise the risk of adverse health effects.

Only under the conditions described in the notification, that is enclosed automated systems and the mandatory use of appropriate personal protective equipment, is the risk of skin sensitisation for these workers considered minimal.

The fuel tank treatment, prepared from the additive package by the addition of solvent, will be packaged into 350-, 500- and 600 mL bottles using automatic packaging equipment. Worker exposure during blending and packaging is expected to be minimal for the reasons discussed above. However, consumers who add the product to fuel tanks could have skin and/or eye exposure from drips or runs left outside of the container after emptying into the fuel tank. The fuel tank treatment will contain <40% of the notified polymer. Personal protection will therefore be required for these workers.

Fuel transporters, service station workers and mechanics will receive negligible exposure because of the very low concentration of notified polymer present in the final fuel. The risk of skin sensitisation for these workers is minimal.

9.2.5. Public health – risk characterisation

No significant public exposure to the notified polymer in additive is anticipated during transport and product formulation. Members of the public may, however, make dermal and possibly ocular contact with the notified polymer when using petrol or aftermarket fuel tank treatments, which contain the notified polymer. The amounts to which the public are likely to be exposed is expected to be small and exposure are expected to be brief and intermittent. Inhalation exposure is expected to be minimal, as the notified polymer is unlikely to pose a significant hazard given its anticipated low toxicity, low concentration in petrol for consumer use and high molecular weight. Based on the use pattern and hazard, it is considered that the notified polymer will not pose a significant risk to public health when used in the proposed manner.

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:

R36/38	Irritating to the eyes and skin
R43	May cause sensitisation by skin contact

and

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.

- Skin irritant Category 2
- Eye irritant Category 2B
- Skin sensitisation Category 1

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use and disposal 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 Negligible Concern to public health when used as described in the notification.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of 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.

11.2. Label

The label for the notified polymer 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 Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following hazard classification for the notified polymer:
  - R36/38 - Irritating to the eyes and skin
  - R43 - May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified polymer:
  - [≥1% notified polymer]: R43 - May cause sensitisation by skin contact;
  - [≥20% notified polymer]: R43 - May cause sensitisation by skin contact and Irritating to the eyes and skin.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe practices to minimise occupational

exposure during handling of the notified polymer as introduced:
- Minimise spills and drips

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced and as diluted for use in the fuel tank treatment product:
  - Chemical resistant gloves
  - Protective clothing
  - Safety goggles

  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.

Environment

Disposal

- Waste product may be hazardous and may require specific waste disposal management in accordance with State/Territory waste disposal regulations. Waste materials containing the notified polymer should be incinerated. Emptied imported drums containing resides of the notified polymer should be sent for drum reconditioning (with wastewater treatment and incineration or concentrated waste) for drum recycling or metal recycling. Emptied aftermarket containers with residues of the notified polymer should be disposed of to landfill or recycled.

Emergency procedures

- Spills/release of the notified substance should be handled by controlling the source of the spill/leak, containing the spill/leak to prevent further environmental release to soils surface waters or groundwater. Keep spill out of sewerage system, stormwater and all bodies of water. Clean up spill as soon as possible. Use appropriate techniques such as non-combustible adsorbent material or pumping. Where feasible and appropriate, remove contaminated environmental media (eg. soil). Place contaminated materials in labelled, sealable containers for storage, handling, transportation and appropriate disposal.

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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