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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Ethene, ethoxy-, polymer with 1-(ethenyloxy)-2-methylpropane, hydrogenated (PVE)

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Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Apollo Resources Pty Ltd
Level 32, Central Plaza One Building
345 Queen Street, Brisbane QLD
ABN: 52 003 671 707

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

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

Dissociation constant
Particle size
Flammability
Oxidising properties
Acute inhalation toxicity
Induction of germ cell damage

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
None

NOTIFICATION IN OTHER COUNTRIES
USA and Korea

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Ethene, ethoxy-, polymer with 1-(ethenyloxy)-2-methylpropane, hydrogenated

OTHER NAME
FVC-32

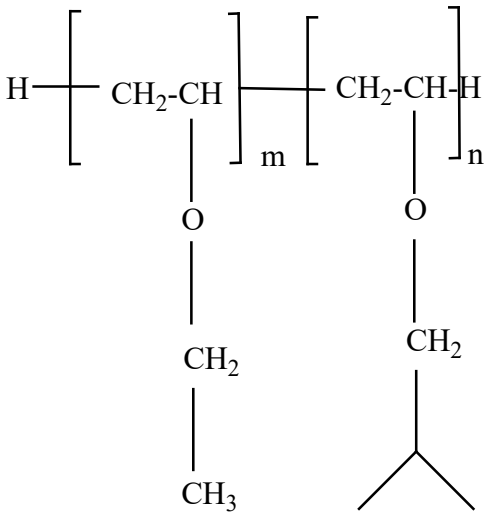
OTHER NAME
PVE

OTHER NAME
Alkyl poly-ether

CAS NUMBER
167257-58-1

MOLECULAR FORMULA
$(C_4H_8O)m . (C_6H_{12}O)n . H_2$ where m+n = 5 ~ 41, average m/n = 1/9 ~ 9/1

STRUCTURAL FORMULA



MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)	735
Weight Average Molecular Weight (Mw)	915
Polydispersity Index (Mw/Mn)	1.25
% of Low MW Species <1000	100
% of Low MW Species <500	50

SPECTRAL DATA

METHOD UV/Visible, Infra Red, ^{1}H-NMR and ^{13}C-NMR spectra, Gas Chromatography
Remarks Ultra Violet spectrum: λmax = 276 and 283 nm in n-Hexane
IR peaks: 2980, 2880, 1480, 1450, 1360, 1100 cm^{-1}
NMR spectra: The signals correspond to the expected structure of the notified polymer.

3. COMPOSITION

DEGREE OF PURITY
>99.9%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

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

Chemical Name 1,1,3,5-Tetraalkyloxybutane (Alkyl = ethyl and/or 2-methyl-1-propyl)
CAS No. Not provided *Weight %* <0.1

Chemical Name 1,1,3-Trialkyloxyhexane (Alkyl = ethyl, etc.)
CAS No. Not provided *Weight %* <0.1

ADDITIVES/ADJUVANTS
None

POLYMER CONSTITUENTS

Chemical Name	*CAS No.*	*Weight % starting*	*Weight % residual*
Ethoxyethene	109-92-2	67	<0.1
1-(ethenyloxy)-2-methylpropane	109-53-5	33	<0.1
Hydrogen	1333-74-0	<0.5	<0.1

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
PVE will not be manufactured in Australia. It will be imported by the notifier in 200 L steel drums. For small volume uses (charging smaller number of refrigerator units), PVE may also be imported in 1 L and 4 L cans.

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

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

USE
PVE will be used as a lubricating oil for compressors in refrigerators.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Apollo Resources Pty Ltd
Level 32, Central Plaza One Building
345 Queen Street, Brisbane QLD

TRANSPORTATION AND PACKAGING
The notified polymer will be imported into Australia from overseas. It will be transported to Australia by sea and then transported by truck or rail to the importers.

The polymer will be transported into Australia in two ways:
1. Contained within sealed refrigerator units; and
2. In 1 L, 4 L containers or 200 L steel drums for filling in the refrigeration units.

5.2. Operation description

PVE will be used as a lubricating oil for refrigerator compressors. It will not be subjected to any further modification or dilution in Australia, but will be used as received from overseas. The drums containing the notified polymer will be transferred from the ships into trucks, which will transport them to the importer's warehouse.

At the production site, the notified polymer (lubricating oil) will be filled into compressor units of refrigerators. One compressor may need up to 2 L of PVE. The procedures relating to charging the lubricating oil will vary depending on the size of production (number of refrigerators). With the smallest size of production, the lubricating oil is poured manually to the filler opening of the compressors directly from the cans (1L or 4L). With large size (numbers) of filling, hoses are connected from PVE drums to compressor units of the refrigerators and charging to the compressors is conducted by automated machinery.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Import and Distribution of Product			
Transport driver inwards	2	4 hours/day	10 days/year
Warehouse storemen	~5	3 hours/day	20 days/year
Transport drivers outwards (empty drums and refrigerators)	2	4 hours/day	10 days/year
Local Use by lubrication chargers			
PVE chargers	3	8 hrs/day	300 days/year

Exposure Details
Transport and storage
Exposure to the notified polymer is not expected during the importation, warehousing or transport of the notified polymer except in cases where packaging is accidentally breached or where the polymer leaks out of the refrigerator units.

At the production site, the refrigerator compressors are charged with the required amount of the notified polymer and sealed. The filling system is automated, therefore exposure during this process is expected to be minimal. When smaller numbers of refrigerators need to be charged, the notified polymer may be poured manually into the compressor units. Dermal, inhalation and ocular exposure can occur during the charging process. However, exposure to significant amounts of the notified polymer will be limited due to the engineering controls and personal protective equipment worn by workers. Use of local exhaust ventilation and good general extraction is indicated. The notifier has indicated that in places where concentrations of particulates and solvent vapours cannot be maintained below the OEL, workers will wear suitable respiratory protection.

Workers may also be exposed to the polymer via the dermal and ocular routes while cleaning and rinsing equipment using recirculated solvent.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified polymer is imported in 200L steel drums or possibly in 1L and 4L cans. No release is expected as the notified polymer is not manufactured or formulated in Australia but used as is.

RELEASE OF CHEMICAL FROM USE
In the rare event of an accident during transport of the substance for industrial use, the substance must be collected and disposed of via landfill. During the charging of PVE to the compressor, the only possible release is limited accidental spill. In such cases waste polymer is swept up with absorbent material and disposed of by incineration. The filling line may be cleaned once a year at most using a solvent. The waste solvent will be disposed of by incineration.

In the case of leakages out of the compressor during the refrigerators' useful life, the lubricant oil will be contained with non-combustible absorbent materials e.g. sand earth, vermiculite, diatomaceous earth and placed in container to be disposed by landfill. When the cooling/freezing systems are disposed of, the lubricating oil is treated as waste which will be disposed of by incineration or landfill. Recycling of the notified polymer is usually not attempted. Containers used for transportation may retain 0.1-0.5% of the notified polymer which are disposed of by licensed company as industrial waste and cleaned for re-use.

5.5. Disposal
All waste will be disposed of by landfill or by incineration

5.6. Public exposure
The notified polymer is to be used in refrigerators as a lubricant. It will not be sold to the general public. The lubricating oil will be sealed in the compressor units of the refrigerators and the general public will not come in contact with it unless it leaks out of the compressor.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Colourless viscous liquid

Freezing Point Less than -25ºC

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks The substance was found to thicken but not solidify as the temperature was decreased to –25ºC.
TEST FACILITY Huntingdon Life Sciences (2003a)

Boiling Point Could not be determined.

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks The boiling point of the substance was not determinable as it decomposed at temperatures above approximately 200ºC without boiling.
TEST FACILITY Huntingdon Life Sciences (2003a)

Density 920 kg/m^3

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks The relative density of the notified polymer was determined relative to purified water using a pyknometer at 20ºC
TEST FACILITY Huntingdon Life Sciences (2003a)

Vapour Pressure 2.6 x 10^{-6} kPa at 25ºC

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks The vapour pressure was determined using a vapour pressure balance. Two runs were performed between temperatures of 20 and 49ºC with pressure being kept at <1 X 10^{-5} Torr. The vapour pressure was determined by extrapolation to a liner plot of log Vp versus 1/T(ºk) at 25ºC.
TEST FACILITY Huntingdon Life Sciences (2003a)

Water Solubility 0.038 g/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks A preliminary test was conducted by visual assessment and the solubility was estimated to be <10 mg/L. The definitive test was conducted using a modified flask method employing slow stirring. Total organic carbon (TOC) content analysis was employed in the absence of a sufficiently sensitive method. Given the observations from the preliminary test, it is evident that the measured solubility of 38 mg/L is attributable to low molecular weight species of the notified polymer.
TEST FACILITY Huntingdon Life Sciences (2003a)

Hydrolysis as a Function of pH Not determined

Remarks The hydrolysis of the test substance was not examined due to its low water solubility and the lack of a sufficiently sensitive method of analysis. Further, PVE does not contain any hydrolysable functional groups.

Partition Coefficient (n-octanol/water) log Pow >6 at 20ºC

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks	A preliminary Partition coefficient was calculated using a LOGKOW computer program (Version 1.63, Syracuse Research Corporation). Based on the solubility of the notified polymer in n-octanol and the determined solubility of 38 mg/L in water, the estimated log Pow was determined to be >4.4. However, it is evident that the more representative higher molecular weight species will have a log Pow of >6. Definitive testing was not conducted as it was considered that the log Pow of PVE would fall outside the scope of the methods normally used.
TEST FACILITY	Huntingdon Life Sciences (2003a)

Adsorption/Desorption log K_{oc} >2.8

METHOD	OECD 121 - Using correlation with water solubility. EEC Method C19
Remarks	A value of the absorption coefficient was estimated based on an empirical relationship with the water solubility of 38 mg/L attributed to low molecular weight species.
TEST FACILITY	Huntingdon Life Sciences (2003a)

Dissociation Constant Not determined.

Remarks	Not applicable due to low water solubility. PVE contains no functional groups likely to dissociate.

Particle Size Not determined

Remarks	Not applicable as the substance is a liquid.

Flash Point 172ºC.

METHOD	EC Directive 92/69/EEC A.9 Flash Point.
Remarks	None.
TEST FACILITY	Huntingdon Life Sciences (2003a)

Flammability Limits Not determined

Remarks	This test was not conducted as the low vapour pressure indicated that a negative result would be obtained.

Autoignition Temperature 366ºC

METHOD	92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks	None.
TEST FACILITY	Huntingdon Life Sciences (2003a)

Explosive Properties Not explosive.

METHOD	EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks	Does not contain any chemically unstable or highly energetic groups that might lead to an explosion.
TEST FACILITY	Huntingdon Life Sciences (2003a)

Reactivity Stable under normal environmental conditions.

Remarks	When handled and stored appropriately no dangerous reactions are known. No oxidizing properties.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*

Rat, acute oral LD50 >2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity
Rat, acute inhalation	Test not conducted
Rabbit, skin irritation	irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation.
Rat, repeat dose oral toxicity – 28 days.	NOEL= 250 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Mammalian Chromosome Aberration Test	non genotoxic
Genotoxicity – in vivo	Test not conducted

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	No control animals were included in this study. The test substance was administered to each rat by oral gavage using a syringe and plastic catheter.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
Group I	5 females/5 males	2000	None

LD50	>2000 mg/kg bw
Signs of Toxicity	Piloerection, hunched posture in all animals and increased salivation in all females.
Effects in Organs	None.
Remarks - Results	Recovery was complete by Day 2.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	Huntingdon Life Sciences Ltd (1997a).

7.2. Acute toxicity - dermal

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/Sprague-Dawley.
Vehicle	None
Type of dressing	Semi-occlusive.
Remarks - Method	No control animals were included in this study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
Group I	5 females/5 males	2000	None

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	None
Signs of Toxicity - Systemic	Low body weight gains were recorded in some female rats.
Effects in Organs	None
Remarks - Results	None.

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

TEST FACILITY Huntingdon Life Sciences Ltd (2003b).

7.3. Acute toxicity - inhalation

Data on inhalation toxicity was not provided. Variation of Schedule Requirements (acute inhalation toxicity) was requested by the notifier, due to the low vapour pressure. In addition, the high viscosity makes it unlikely that aerosols of inhalable size would be generated under normal use conditions. The notified polymer is slightly soluble in water and oral toxicity study with the polymer indicated no evidence that it is absorbed from the gastro-intestinal tract.

7.4. Irritation – skin

TEST SUBSTANCE Notified polymer

METHOD	
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 females
Vehicle	None
Observation Period	9 days
Type of Dressing	Semi-occlusive.
Remarks - Method	There were no deviations from the protocol.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	2	2	1	2	8 days	0
Oedema	2	2	0	2	8 days	0

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

Remarks - Results A single application to intact skin for 4 hours elicited very slight to well defined dermal irritation in all animals.

CONCLUSION The notified polymer is irritating to the skin.

TEST FACILITY Huntingdon Life Sciences Ltd (1997b).

7.5. Irritation - eye

TEST SUBSTANCE Notified polymer

METHOD	
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Observation Period	3 days
Remarks - Method	One animal was treated in advance of the others, to ensure that if a severe response was produced, no further animals would be exposed.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.3	0.3	0.3	2	24 hr	0
Conjunctiva: chemosis	0	0	0	1	1 hr	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results: No corneal damage or iridial inflammation was observed. Transient very slight to well defined conjunctival irritation only was observed.

CONCLUSION: The notified polymer is slightly irritating to the eye.

TEST FACILITY: Huntingdon Life Sciences Ltd (1997c).

7.6. Skin sensitisation

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 406 Skin Sensitisation – Maximisation test.
EC Directive 96/54/EC B.6 Skin Sensitisation - Maximisation test.

Species/Strain: Guinea pig/Dunkin/Hartley.

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: 100% PVE
topical: 100% PVE

MAIN STUDY

Number of Animals: Test Group: 5 females Control Group: 10 females

INDUCTION PHASE: Induction Concentration:
intradermal: 100% PVE
topical: 100% PVE

Signs of Irritation: Necrosis occurred at site receiving FCA in both test and control animals.

CHALLENGE PHASE

1st challenge: intradermal: None
topical: 100% PVE and 50% (v/v) in Alembicol D

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	100	0	0	-	-
Control Group	100	0	0	-	-

Remarks - Results: All test animals gave negative responses to 100% PVE.

CONCLUSION: There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

TEST FACILITY: Huntingdon Life Sciences Ltd (2003c).

7.7. Repeat dose toxicity

TEST SUBSTANCE: Notified polymer

METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	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: 0 days.
Vehicle	Corn oil
Remarks - Method	Urinalysis measurements were not performed.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5 males / 5 females	0	None
II (low dose)	5 males / 5 females	50	None
III (mid dose)	5 males / 5 females	250	None
IV (high dose)	5 males / 5 females	1000	None
V (control recovery)	None	-	-

Mortality and Time to Death

There were no unscheduled deaths during the treatment period.

Clinical Observations

There were no clinical signs observed during the study that were considered to be indicative of a reaction to treatment. The group mean bodyweight gain and mean motor activity times revealed inter group differences between control and treated groups, however there was no dosage relationship apparent between the treated groups and there was no consistent trend noted between the sexes.

Laboratory Findings – Clinical Chemistry and Haematology

Low alanine aminotransferase (ALT) values (statistically significant) were observed among all treated female groups and for males receiving 1000 mg/kg/day. However, the differences did not follow a dose-related trend and the majority of individual values for females receiving 50 or 1000 mg/kg/day were within the individual range of the female controls. Lower than control aspartate aminotransferase (AST) values were also noted for both sexes receiving 1000 mg/kg/day, with the female value attaining statistical significance.

In the 1000 mg/kg/day group, females had slightly higher mean platelet count (statistically significant) and male rats had higher prothrombin time (PT) and higher activated partial thromboplastin time (APTT) when compared with those of their respective control groups.

Effects in Organs

All treated female groups had statistically significantly higher group mean thymus weights (adjusted for bodyweight) when compared with controls. However, the group mean did not follow a dosage related trend and no treatment-related change in thymus weights were noted among the male treated groups. As there were no changes in the microscopic pathology of the thymus, the difference in organ weights was not considered to be treatment-related.

Remarks – Results

Treatment at 250 mg/kg/day did not result in any treatment-related findings. At 1000 mg/kg, apart from the changes in AST and platelets, all changes observed were minor, within historical controls or lacking dose relationship. In the absence of corroborating findings, the changes were not considered to be treatment related by the study authors.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 250 mg/kg bw/day in this study, based on clinical chemistry and haematological changes at higher dose.

TEST FACILITY Huntingdon Life Sciences Ltd (2003d).

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Pre incubation procedure/Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2uvrA.
Metabolic Activation System	Induced rat liver microsomal fraction (S9)
Concentration Range in Main Test	a) With metabolic activation: 313-5000 µg/plate. b) Without metabolic activation: 313-5000 µg/plate.
Vehicle	Ethanol.
Remarks - Method	A preliminary range-finding test was performed with 5, 15, 50, 150, 500, 1500 and 5000 µg/plate with and without metabolic activation. Two independent tests were performed, the first by the plate incorporation procedure and the second by the pre-incubation procedure.
RESULTS	
Remarks - Results	No cytotoxicity was observed at any dose level. Revertant frequencies for all doses of the notified polymer in all tested strains with and without S9, 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	Huntingdon Life Sciences Ltd (1997d).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Human male donors
Cell Type/Cell Line	Cultured human peripheral lymphocytes
Metabolic Activation System	S9 fraction from Aroclor 1254-induced rat liver
Vehicle	Ethanol
Remarks - Method	A dose range finding test and two independent cytogenetic assays were conducted. The second cytogenentic assay dose levels were selected based on the inhibition of cell growth of the dose range finding test and the first cytogenetic assay. 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*	*Harvest Time*
Absent			
Test 1	39.06, 78.13, 156.25, 312.5, 625, 1250*, 2500* and 5000*.	3	20

Test 2	156.25, 312.5, 625, 1250*, 2500* and 5000*.	20	20
Present			
Test 1	39.06, 78.13, 156.25, 312.5, 625, 1250*, 2500* and 5000*.	3	20
Test 2	625, 1250*, 2500* and 5000*.	3	20

*Cultures selected for metaphase analysis.

Remarks - Results

Test 1
In both the absence and presence of S9 mix, the notified polymer failed to cause a reduction in the mitotic index compared to the solvent control value. The quantitative analysis for polyploidy showed no increase in the number of polyploid metaphase figures when compared to the solvent control. The notified polymer did not cause statistically significant increase in the proportion of cells with chromosomal aberrations at any dose level, either with or without S9 mix.
Test 2
In the absence of S9 mix, the notified polymer caused a reduction in the mitotic index to 56% of the solvent control value at 5000 µg/mL. In the presence of S9 mix, the notified polymer failed to cause a reduction in the mitotic index. The quantitative analysis for polyploidy showed no increase in the number of polyploid metaphase figures when compared to the solvent control. The notified polymer did not cause statistically significant increase in the proportion of cells with chromosomal aberrations at any dose level, either with or without S9 mix.
In both tests, the positive control compounds, mitomycin C and cyclophosphamide, caused large increases in the proportion of aberrant cells.

CONCLUSION: The notified polymer was not clastogenic to to human peripheral lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY: Huntingdon Life Sciences Ltd (2002).

7.10. Genotoxicity – in vivo

No test report was provided.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 301B Ready Biodegradability: CO_2 Evolution Test.

Inoculum: Activated sludge from Oakley sewage treatment works
Exposure Period: 29 days
Auxiliary Solvent: None
Analytical Monitoring: None
Remarks - Method: The notified polymer was added to two vessels containing activated sludge to give a nominal test concentration of 10 mg C/L Two control vessels contained inoculated mineral salts alone and one contained inoculated mineral salts medium plus the reference substance sodium benzoate (10 mg C/L). An additional mixture containing sodium benzoate (10 mg C/L) and the notified polymer (10 mg C/L) was used to assess the inhibitory effect of test substance on the activity of the microbial inoculum. CO_2 produced by each culture was trapped in bottles containing barium hydroxide. The residual barium hydroxide was determined at intervals by

titrations. The temperature and pH of the tests were within acceptable limits over the 29 days exposure.

RESULTS

Test substance		*Reference Substance*	
Day	*% degradation*	*Day*	*% degradation*
29	<2	11	60
		29	71

Remarks - Results: Biodegradation in mixtures containing the notified polymer was negligible and had achieved at most 2% of the theoretical value on day 29 of the test. The results confirmed that the notified polymer was not inhibitory to the activity of the microbial inoculum. Cumulative levels of CO_2 production in the controls after 29 days confirm that the inoculum was viable. The degradation of sodium benzoate had achieved 60% of its theoretical CO_2 after 8 days confirming the test was valid.

CONCLUSION: The notified polymer is considered not readily biodegradable.

TEST FACILITY: Huntingdon Life Sciences Ltd (2003e)

8.1.2. Bioaccumulation

It is considered that the notified polymer has the potential to bioaccumulate in the aquatic environment as the log Pow>6. Further, the notified polymer is not readily biodegradable and is therefore likely to persist in the environment.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 203 Fish, Acute Toxicity Test – semi-static exposure conditions.
EC Directive 92/69/EEC C.1 Acute Toxicity for Fish

Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 h
Auxiliary Solvent	None
Water Hardness	180 mg $CaCO_3$/L
Analytical Monitoring	TOC and DOC analysis
Remarks – Method	Groups of seven juvenile fish were exposed to Water Accommodated Fractions (WAFs) of the notified polymer at nominal loading rates of 4.27, 9.39 20.7 and 100 mg/L. The mixtures were stirred overnight in darkness and then allowed to stand for at least 1 h before the aqueous phase were removed and used in the test. The WAFs were clear and colourless. In addition to observations on mortality at 15 minutes, 2, 4, 24, 48 72 and 96 h, subjective assessment on sub-lethal effects such as hyperventilation, darkened pigmentation, darkened eye orbits and nervous erratic swimming were also made. The pH, temperature, total hardness and dissolved oxygen concentrations remained within acceptable limits during the test.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nomina loading ratel	*Mean measured**		*2h*	*24h*	*48h*	*72h*	*96h*

Control	-	7	0	0	0	0	0
4.27	0.7	7	0	0	0	0	0
9.39	1.2	7	0	0	0	0	0
20.7	3.2	7	0	0	0	0	0
45.5	5.0	7	0	0	0	0	0
100	9.9	7	0	0	0	2	3

* mean measured level of the notified polymer based on DOC analysis

LC50	>9.9 mg/L at 96 hours.
NOEC	5 mg/L at 96 hours.
Remarks – Results	Based on the measured levels of DOC the concentrations of the notified polymer ranged between 5-22% of their nominal values, giving overall mean measured levels of 0.7, 1.2, 3.2, 5.0 and 9.9 mg/L. After 96 h, the highest loading rate at which no mortality occurred was 45.5 mg/L. At the highest loading rate (100 mg/L) employed in the test, 43% mortality occurred.

CONCLUSION The notified polymer is considered to be at worst toxic to fish.

TEST FACILITY Huntingdon Life Sciences Ltd (2003f)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test.
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	260 mg $CaCO_3$/L
Analytical Monitoring	TOC and DOC analysis
Remarks - Method	Four replicates of five animals per vessel were exposed for 48 h to WAFs of the notified polymer at nominal loading rates of 4.27, 9.39, 20.7, 45.5 and 100 mg/L. The test medium was prepared by the direct addition of the test substance to Elendt M4 medium. The mixture was stirred overnight in darkness and then allowed to stand for approximately 90 minutes before the aqueous phase was removed and used in the test. The exposure concentrations of the notified polymer were monitored using Total (TOC) and Dissolved Organic Carbon (DOC) analysis. Observations of the *Daphnia* for immobilization in each control and test group were made after 24 and 48 h. The pH, temperature, total hardness and dissolved oxygen concentrations remained within acceptable limits during the test.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*	*Four replicates of 5 animals*	*24 h [acute]*	*48 h [acute]*
Control	-	20	0	0
4.27	-	20	0	0
9.39	-	20	0	0
20.7	1.8	20	0	0
45.5	4.1	20	0	0
100	8.2	20	4	14

LC50	7.02 mg/L at 48 hours (95% CL 4.1 and 8.2 mg/L)
NOEC	4.1 mg/L at 48 hours
Remarks - Results	Based on the measured levels of TOC, the concentrations of the notified polymer ranged between 11 and 34% of their nominal values, with overall mean measured levels of 1.2, 1.3, 4.3 6.4 and 12.1 mg/L. Based on the measured levels of DOC at the three highest levels, the concentrations of the notified polymer ranged between 6 and 11% of nominal, with overall mean measured levels of 1.8, 4.1 and 8.2 mg/L. The two lowest levels were found to be unreliable as the DOC levels were below or similar to those found in the control. After 48 h, the highest nominal loading rate at which no immobilization occurred was 45.5 mg/L. At the highest loading rate (100 mg/L) employed in the test, 70% immobility occurred.
CONCLUSION	The notified polymer is considered to be toxic to *Daphnia magna.*
TEST FACILITY	Huntingdon Life Sciences Ltd (2003g)

8.2.3. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 211 *Daphnia magna*, Reproduction Test (Semi-static exposure conditions)
Species	*Daphnia magna*
Exposure Period	21 days
Auxiliary Solvent	None
Water Hardness	234-261 mg $CaCO_3$/L
Analytical Monitoring	TOC and DOC analysis
Remarks - Method	Groups of ten, individually-housed Daphnia were exposed for 21 days to WAFs of the notified polymer at nominal loading rates of 0.298, 0.954, 3.05, 9.77, 31.3 and 100 mg/L. The test media were prepared by the direct addition of the test substance to Elendt M4 medium. The mixture was stirred overnight in darkness and then allowed to stand for approximately 2 h before the aqueous phase (WAF) was removed for use in the test. The WAFs were clear and colourless except at the highest concentrations where it was an off-white hazy emulsion. The exposure concentrations of the notified polymer were monitored using TOC and DOC analysis. Daily records were maintained for mortality, physical appearance, number of gravid animals, live and dead neonates and the presence of aborted eggs and moulted carapaces. The pH, temperature, total hardness and dissolved oxygen concentrations remained within acceptable limits during the test.

RESULTS

Concentration mg/L		*Number of D. magna*	*% Mortality 21 days*
Nominal	*Actual*		
0.298	0.3	10	0
0.954	0.7	10	10
3.05	0.8	10	10
9.77	1.8	10	10
31.3	4.4	10	10
100	10.4	10	80

Exposure concentration (mg/L)		*Cumulative number neonates/adult*	
Nominal loading rate	*Measured concentration*	*Mean*	*Standard Deviation*

Control	-	88.2	13.0
0.298	0.3	86.1	13.7
0.954	0.7	81.2	9.83
3.05	0.8	80.4	9.81
9.77	1.8	75.1	8.30
31.3	4.4	31.6	16.3
100	10.4	4.5	6.36

EC10	1.59 mg/L at 21 days (95% CL 0.97 and 2.60 mg/L)
EC20	2.16 mg/L at 21 days (95% CL 1.53 and 3.05 mg/L)
EC50	3.63 mg/L at 21 days (95% CL 3.10 and 4.18 mg/L)
NOEC	0.8 mg/L at 21 days

Remarks - Results

Based on the measured levels of DOC, the concentrations of the notified polymer in WAFs at the three highest test concentrations ranged between 1.6 and 12 mg/L At 0.298 to 3.05 mg/L the measured levels were found to be unreliable as the DOC levels were close to those found in the control. Based on the total numbers of neonates produced by the surviving parental Daphnia by Day 21, there were no significant differences at 0.3 to 0.8 mg/L of the measured concentration compared to the control. Statistically significant reductions in neonate production were observed at 1.8, 4.4 and 10.4 mg/L. The size of the surviving adults at the end of the test was affected at 1.8 mg/L and above.

CONCLUSION

The notified polymer affected the ability of the parental generation to produce neonates at 1.8 mg/L and above.

TEST FACILITY

Huntingdon Life Sciences Ltd (2003h)

8.2.4. Algal growth inhibition test

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	Green alga (*Selenastrum capricornutum*)
Exposure Period	72 hours
Concentration Range	
Nominal	100 mg/L
Actual	8.2 mg/L
Auxiliary Solvent	
Analytical Monitoring	TOC and DOC analysis

Remarks - Method

Six replicate algal cultures, with an initial cell density of 1 X 10^4/mL were exposed to a WAF of the notified polymer at a nominal loading rate of 100 mg/L. The test medium was prepared by the direct addition of the test substance to OECD algal medium. The mixture was stirred overnight in darkness and then allowed to stand for approximately 1 h before the aqueous phase (WAF) was removed. The WAFs were clear and colourless. The exposure concentrations of the notified polymer were monitored using TOC and DOC analysis. Cell numbers were counted daily to monitor growth. The results were expressed in terms of the mean measured DOC concentrations of the notified polymer The pH and temperature remained within acceptable limits during the test.

RESULTS

Biomass	*Growth*

EbC50 *Measured concentration mg/L at 72 h*	*NOEC* *Measured concentration mg/L at 72 h*	*ErC50* *Measured concentration mg/L at 72 h*	*NOEC* *Measured concentration mg/L at 72 h*
>8.2	≥8.2	>8.2	≥8.2

Remarks - Results: Based on the measured levels of DOC, the concentration of the notified polymer ranged from 7-9% of its nominal value during the test, giving an overall mean measured level of 8.2 mg/L. Compared to the control cultures, neither the area under the growth curve nor the growth rate were significantly reduced by the notified polymer at the measured level of 8.2 mg/L.

CONCLUSION: The notified polymer is considered to be at most toxic to alga.

TEST FACILITY: Huntingdon Life Sciences Ltd (2003i)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer is not intended to be manufactured or reformulated in Australia and thus no environmental release is expected from such sites. Release of the lubricant oil containing the notified polymer to the environment is not expected under normal use. Any releases from accidental spillage or during transport would be disposed of by landfill or incineration. Residues from cleaning of the filling line and from the empty import drums will also be disposed of as industrial waste and ultimately be incinerated. Incineration of the waste will destroy the notified polymer with the generation of water vapour and oxides of carbon. In landfill the high K_{ow} ($logP_{ow}$ >6) will limit any leaching and the polymer will slowly degrade. Therefore, environmental exposure in the aquatic compartment is expected to be low from the reported use pattern.

Due to the nature of the release pattern, a predicted Environmental Concentration (PEC) cannot be estimated.

The notified polymer is not readily biodegradable. The abiotic or slow biotic processes are expected to be largely responsible for the degradation of the notified chemical.

9.1.2. Environment – effects assessment

In summary, the aquatic toxicity data indicate:

Algae: 72 h EC50 >8.2 mg/L; NOEC ≥8.2 mg/L
Daphnia magna: 48 h LC50 = 7.02 mg/L (95% CL 4.1 and 8.2 mg/L); NOEC = 4.1 mg/L
Daphnia magna: 21-day EC50 for reproduction = 3.63 mg/L (95% CL 3.10 and 4.18 mg/L); NOEC 0.8 mg/L
Rainbow trout: 96 h LC50 >9.9 mg/L; NOEC = 5 mg/L

The Predicted No Effect Concentration (PNEC) is 80 µg/L, using a safety factor of 10, and the chronic 21 day NOEC of 0.8 mg/L for *Daphnia magna*.

9.1.3. Environment – risk characterisation

The notified polymer will enter environmental compartments indirectly by disposal of waste oil and spillage (to landfill or for incineration). Based on the low import volume of 1 tonne and the widespread and diffuse use of the notified chemical, release to the environment is expected to be low and is unlikely to pose an environmental risk.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

During transport and storage, workers are unlikely to be exposed to the notified polymer unless packaging is breached. In the event of an accident, spills will be removed in accord with the MSDS and government regulations.

There is no blending or reformulation involved. The notified polymer is transferred to the compressor units of refrigerators directly from the containers. The main potential for occupational exposure is during filling the compressor units. Large scale transfer of the notified polymer to the refrigerators is automated. However, exposure to the notified polymer may occur during transfer operations as delivery lines are connected/disconnected from the containers, and during sampling for laboratory analysis.

For smaller size production, the notified polymer is poured manually in the filler opening of the compressor directly from the 1L or 4 L can. Skin contact is expected to be the major route of exposure. Potential for slight, transient eye irritation exists following eye contact. Inhalation will be a very unlikely route of exposure given the low vapour pressure.

The possibility of exposure to drips and spills exists during cleaning and equipment maintenance. Dermal exposure would be the predominant route of occupational exposure to workers during these activities. Workers handling connections or equipment will be properly protected with PPE as recommended in the MSDS.

9.2.2. Public health – exposure assessment

No significant public exposure to the notified polymer is anticipated during transport. It will not be sold to the general public. The lubricating oil will be sealed in the compressor units of the refrigerators and the general public will not come in contact with it unless it leaks out of the compressor, which is highly unlikely.

9.2.3. Human health – effects assessment

The notified polymer was of very low acute oral toxicity (LD_{50}>2000 mg/kg) and low acute dermal toxicity (LD_{50}>2000 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. It showed no evidence of skin sensitisation in guinea pigs.

In a 28-day repeated oral dose study (sub-chronic toxicity) rats received 0, 50, 250 or 1000 mg/kg/day of notified polymer. No treatment related findings were observed at dose level 250 mg/kg/day and below. Slight changes in ALT and AST values (statistically significant) were observed among animals receiving 1000 mg/kg/day. However, the differences did not follow a dosage-related trend and the majority of individual values were within the individual range of the controls. The NOEL determined for the subchronic oral toxicity was 250 mg/kg/day, based on slight haematological and clinical chemistry changes at the higher 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 the notified polymer is skin irritant with risk phrases R38 – Irritating to Skin.

9.2.4. Occupational health and safety – risk characterisation

During importation and transport of the notified polymer in 1 L, 4 L containers or 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 operations (filling of compressor units) at the refrigerator production site are enclosed and automatically operated. However, exposure to

the notified polymer may occur during transfer operations, as delivery lines are connected/disconnected from the import containers, and during sampling for laboratory analysis. Dermal and ocular exposure is possible when filling the compressor units manually (pouring the notified polymer directly into the units), as is likely to happen in low number production. Potential for slight, transient eye and skin irritation exists following eye or skin contact with the notified polymer.

After filling with the notified polymer, the compressor units of the refrigerators are sealed thereby preventing any leakage of the liquid. Exposure to the notified polymer during transport of refrigerators may occur only in the rare cases where the liquid leaks out of the compressor units.

9.2.5. Public health – risk characterisation

No significant public exposure to the notified polymer is anticipated during transport and filling operations. The lubricating oil will be sealed in the compressor units of the refrigerators and the general public will not come in contact with it unless it leaks out of the compressor, which is highly unlikely.

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

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

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 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 NOHSC Chemicals Standards Sub-committee should consider the following [health, environmental and physico-chemical] hazard classification for the notified polymer:
  - R38-Irritating to skin
  - S37/38/39-Wear suitable protective clothing, gloves, and eye/face protection.

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:
  - 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.

Environment

- Do not allow to enter drains or water courses

Disposal

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

Emergency procedures

- Contain and collect spillage with non-combustible absorbent materials e.g. sand earth, vermiculite, diatomaceous earth and place in container for disposal according to local regulators.

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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