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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polyurea grease thickener in Polyrex EM

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Mobil Oil Australia Pty Ltd (ABN 88 004 052 984) of 417 St Kilda Road Melbourne VIC 3004.

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (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, Molecular and Structural Formulae, Molecular Weight, Spectral Data, Purity, Hazardous and Non-hazardous Impurities, and Additives/Adjuvants.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Part B: Vapour Pressure, Hydrolysis as Function of pH, Adsorption/Desorption, Dissociation Constant.
Part C: Acute Inhalation Toxicity, and Bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
USA (1988), EU and Canada (2001).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polyrex EM (12% notified chemical)
Polyurea grease thickener

3. COMPOSITION

DEGREE OF PURITY
High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None are present at above the relevant cut off level for classification of the notified polymer as a hazardous substance

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Import (as a fully formulated grease).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-10	1-10	1-10	1-10	1-10

USE
A thickener agent (12% w/w) used in all-purpose lubricating grease for industrial applications.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Mobil Oil Australia Pty Ltd
Quality Packaging Services Pty Ltd of 535 Somerville Road Sunshine VIC

TRANSPORTATION AND PACKAGING
Polyrex EM containing 12% notified chemical will be shipped and road transported in 174 kg drums and 16 kg pails directly from dockside to a contract packaging company for storage and/or repackaging into end use containers of 2.5 kg tubs and 450 g cartridges. Storage will be in a covered bunded area and in accordance with state legislation.

5.2. Operation Description

The notified chemical will not be manufactured in Australia but will be imported as a component of the fully formulated grease for industrial use with approximately 2-3 shipments per year.

At the contract packaging company in Melbourne, the imported product will be repacked and this will involve pumping the grease from the 174 kg drums (or occasionally from 16 kg pails) into smaller containers with the remnant normally scraped out and placed on top of the next drum, prior to the pump being put into place. The drum pump has a follower plate with a tight seal around the edges, so the drum is usually "clean" at the completion of the run.

During industrial use, the grease will be predominantly applied using grease cartridges in a grease gun. The users crack the seal on the cartridge and place it into the gun. The gun is then applied to "grease nipples" on the relevant piece of equipment being lubricated and the grease is pumped into the bearing until a small amount of fresh grease is seen coming out of the relief system on the opposite side of the bearing.

It is expected that the grease in the bearing will be "lost" over time, and thus collection of used or worn grease for disposal would be unlikely.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Waterside, transport and warehouse workers	small	--	--
Packaging workers	2	40 h/year	every 4-6 months
Industrial end users	large	30 sec/application	every 3-6 months

Exposure Details

During transport and storage, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached. Should a spill occur, it is expected to be contained and collected using suitable absorbents (eg sand), and placed into suitable containers for recovery or disposal in accord with the MSDS and official regulations.

It is estimated that two packaging workers will be potentially exposed to the grease via skin and eye contact due to residues and spillages when they are involved in pumping and metering the imported grease into 2.5 kg tubs and 450 g cartridges or during connecting/disconnecting pump lines from a semi-automated filling machine. During equipment maintenance and cleaning procedures exposure are anticipated to be less frequent and in smaller quantities. The workers will wear suitable protective

clothing, impervious gloves, safety glasses with side shields/chemical goggles, and observe safe work practice. The notifier indicates that adequate ventilation will be in place to prevent workers from breathing mist, dust and particulates. Copies of the MSDS will be readily accessible in all work areas.

A large number of industrial workers will be end users of the grease product, predominantly by means of grease cartridges. During its end use, the cartridges will be applied on a grease gun and pumped into the bearing, exposure of these workers therefore is expected to be confined to dermal contamination with drips and spills when replacing the spent cartridges or while handling equipment components that have been in contact with the grease. Exposure would be minimised by personal protective equipment, industrial hygiene, and good work practices. Grease application using 2.5 kg tubs is also expected to be via enclosed and semi-automated pumps that will be operated by well trained staff.

5.4. Release

RELEASE OF CHEMICAL AT SITE

During repackaging of the 174 kg drums and 16 kg pails, there is approximately 2 kg and 0.4 kg respectively of the grease product remaining in the containers when the pump breaks suction. This equates to <0.5 kg of the notified chemical. It is normal practice for these residues to be collected with a scraper on an extension arm and placed on the top of the next drum prior to attaching the pump. Precautions are taken at the repacking facility to ensure residual material is not released to the environment.

RELEASE OF CHEMICAL FROM USE

During normal use, the grease is generally applied by sealed cartridges and grease guns and is in the form of a semi-solid or paste. Grease guns have a plunger which scrape the walls and ensure efficient emptying of the cartridge. The grease containing the notified chemical therefore is not expected to be released into the environment.

Release of the notified chemical due to spills will be limited and easily contained for disposal due to the physical nature of the grease. If the substance does enter the environment through accidental spillage or release, the low water solubility would indicate that it is unlikely to be mobile in water and enter water supplies.

5.5. Disposal

It is assumed that some waste material will be present in used containers and application devices. Waste greases containing up to 12% of the notified chemical will be disposed of as hazardous waste. This polyurea grease thickener will be part of a long-life grease designed to last with the life of metal parts and virtually all of the grease would be destroyed during recycling of these parts.

5.6. Public exposure

The notified chemical is intended for use in industry only. While the imported grease will be a commercial product, it is expected that use outside industry will be rare or under conditions similar to those for industrial users. Public exposure to the notified chemical therefore will normally only occur in the event of a transport accident or spillage. Such accidents are unlikely.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Off white granules (solid)

Melting Point >190ºC

METHOD	OECD TG 102 Melting Point/Melting Range EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	In duplicate determinations, the notified chemical was observed to darken significantly in colour at >190ºC indicating decomposition. When heating was continued, the orange/amber decomposition product was found to melt at approximately 300ºC to form a dark amber liquid.
TEST FACILITY	Huntingdon Life Sciences (1999)

Density 1030 kg/m^3 at 22ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks A pycnometer method was conducted using heavy petroleum distillate as the displacement liquid.
TEST FACILITY Huntingdon Life Sciences (2001)

Vapour Pressure Not determined

Remarks Determination of vapour pressure was not technically feasible due to the complex composition of the notified chemical. Modelled data using EPIWIN v3.02 (Syracuse Research Corporation 1998) indicate that vapour pressure range is from 8 x 10^{-10} kPa to 8 x 10^{-19} kPa, which is below the limits of all OECD methods.

Water Solubility <3.3x10^{-4} g/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks A flask method was conducted using a loading rate of 100 mg/L with slowly stirring over 7 days so as not to cause the formation of a water-notified chemical emulsion. Samples were removed without centrifugation or filtration for DOC (Dissolved Organic Carbon) analysis with its limit of quantitation claimed to be 3.3x10^{-4} g/L.
TEST FACILITY Exxon (1999a)

Hydrolysis as a Function of pH Not determined

Remarks Test was not conducted due to the low water solubility of the notified chemical. The notified chemical contains functional groups which may undergo hydrolysis, but this is unlikely to occur under the environmental pH range (4-9).

Fat Solubility 100 g/kg or 10% w/w in standard fat simulant at 37°C

METHOD OECD TG 116 Fat Solubility of Solid and Liquid Substances.
Remarks Samples of the test material were stirred in a fat simulant for 3-24 h at 37ºC. After equilibration, the samples were transferred into a sintered glass crucible where they were washed with hexane to complete the transfer and remove residual fat. Crucibles were then heated to constant weight, with the difference between the amount of test material initially added and the final mass after heating taken to be the amount of test material that dissolved in the fat. However, it should be noted that under this condition of test it is impossible to distinguish between the solubility of the chemical in the fat simulant and in hexane. By gravimetric analysis, the measured solubility figures were 0.2 g/kg and 1.2 g/kg at the 0.1 g/50 g and 1 g/50 g test levels respectively. The results increase with test concentration, indicating that the notified chemical contains at least one component which is soluble in fat simulant and/or hexane. These components comprise approximately 10% w/w of the notified chemical.
TEST FACILITY Huntingdon Life Sciences (2001)

Partition Coefficient (n-octanol/water) log Pow (component A) = 4.0
log Pow (component B) = 4.1
log Pow (component C) = 5.1
log Pow (component D) > 6.0

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks HPLC Method. Reference substances covered log Pow range 0.3-6.2. The notified chemical eluted as four component groups with differing log Pow values as above.
TEST FACILITY Exxon (1999b)

Adsorption/Desorption Not determined

Remarks Test was not conducted due to the low water solubility of the notified chemical. Given the relatively high partition coefficients the notified chemical would be expected to adsorb strongly to sediment and sludge.

Dissociation Constant Not determined

Remarks The notified chemical contains no functional groups which will dissociate under the environmental pH range (4-9).

Particle Size

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (μm)	*Mass (%)*
<10	0
10 – 75	7
75 – 125	7
>125	86

Remarks In duplicate tests, the results indicate that 7% by mass of the notified chemical is <75 μm.
TEST FACILITY Huntingdon Life Sciences (2001)

Flash Point Not applicable

Remarks The notified chemical is a solid.

Flammability Limits Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks The notified chemical melted, and the molten substance ignited and propagated a flame over 200 mm in 31 min 10 sec.
TEST FACILITY Huntingdon Life Sciences (1999)

Autoignition Temperature No self ignition to 400°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks There was no significant exothermic reaction of the notified chemical, indicating that it does not self-ignite at <400°C.
TEST FACILITY Huntingdon Life Sciences (2001)

Explosive Properties Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks In thermal sensitivity tests, the notified chemical burned with yellow flame without explosion over the test period. Mechanical (shock and friction) sensitivity tests were negative.
TEST FACILITY Huntingdon Life Sciences (2001)

Oxidising Properties Not oxidising

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks The notified chemical and cellulose mixtures burned with yellow flame, but not to completion.
TEST FACILITY Huntingdon Life Sciences (2001)

Reactivity Stable under normal environmental conditions

Remarks The notified chemical may react with strong oxidisers and decompose under extreme heat or high energy sources of ignition.

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	no data available
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test	no evidence of sensitisation (100% notified chemical)
Rat, repeated oral dose toxicity - 28 days	NOAEL = 1000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	non genotoxic
Genotoxicity – in vivo studies	no data available
Pharmacokinetic/Toxicokinetic studies	no data available
Developmental and reproductive effects	no data available
Carcinogenicity	no data available

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain Rat/Crl:CDBR
Vehicle Corn oil
Remarks - Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	0/10

LD50 >2000 mg/kg bw
Signs of Toxicity All animals survived, gained weight, and were free of observable abnormalities over the 14-day test period.
Effects in Organs 3/5 males and 1/5 female displayed discoloured kidneys at the gross postmortem examination. The remaining animals showed no abnormalities.
Remarks - Results None.

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

TEST FACILITY Exxon (1999c)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Notified chemical

METHOD EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain Rat/Crl:CDBR
Vehicle Reverse osmosis water 1 mL (moistened)
Type of dressing Occlusive
Remarks - Method No significant protocol deviations, except the use of reverse osmosis

water.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	0/10

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	1/5 female was observed with a scratch (mechanical damage) on the dose site on Day 7.
Signs of Toxicity - Systemic	All animals survived, gained weight, and were free of clinical signs of toxicity over the 14-day test period, except 1/5 female was observed with scabs on the trunk from Day 7-14.
Effects in Organs	No observable abnormalities were noted at the gross postmortem examination.
Remarks - Results	None.

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

TEST FACILITY Exxon (1999d)

7.3. Acute toxicity – inhalation

Remarks Test was not conducted due to low volatility of the notified chemical.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Vehicle	Reverse osmosis water 0.5 mL (moistened)
Observation Period	7 days
Type of Dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations.

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	0.7	0.3	0.0	1	72 h	0
Oedema	0.0	0.0	0.0	0	0 h	0

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

Remarks - Results Grade 1 erythema together with an apparent self-inflicted scratch was observed in one animal at 1h, 24h, and 48 h evaluations. A second animal had slight erythema at 72 h observation. Desquamation was noted in one animal at 72 h and in two animals at the Day 7 evaluations. All animals were clear of erythema and oedema on Day 7.
Primary irritation index = 0.3 (slightly irritating).

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY Exxon (1999e)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals 3 males
Observation Period 5 days
Remarks - Method No significant protocol deviations.

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	0	0.3	1	24 h	0
Conjunctiva: chemosis	0	0	0	0	0 h	0
Conjunctiva: discharge	0	0	0	0	0 h	0
Corneal opacity	0	0	0	0	0 h	0
Iridial inflammation	0	0	0	0	0 h	0

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

Remarks – Results Grade 1 redness was observed in all three animals at 1 h, and remained in one animal for 24 h post treatment. Residual test material and dye retention of the palpebral conjunctiva were noted in the eye of all animals at 1 h and 24 h respectively. Dye retention of the nictitating membrane was noted in one animal at the 24 h observation. One animal still had residual test material around the eye (including eyelashes) at this observation. All animals were free of abnormalities at the 48 and 72 hour observations. No iridial responses were observed during the study.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Exxon (1999f)

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD EC Directive 96/54/EC B.6 Skin Sensitization – Buehler Test.
Species/Strain Guinea pig/CRL:(HA)BR-Hartley
PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: 100% test substance
MAIN STUDY
Number of Animals Test Group: 20 Control Group: 10
INDUCTION PHASE Induction Concentration:
topical: 100% test substance
Signs of Irritation No signs of irritation were observed in test and control animals following topical occlusive inductions on Day 0, 7 and 14.
CHALLENGE PHASE
1st challenge topical: 100% test substance
Remarks - Method Protocol deviations such as clipping irritation control animals on Day 1 (instead of Day 0) and performing the 24 h evaluations at 31 h after dosing were not considered to have adverse effects on the study results or integrity.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	100%	0/20	0/20
Control Group	100%	0/10	0/10

Remarks - Results: No dermal responses were observed at 24 and 48 h after challenge. One treated group animal was slightly emaciated on Day 21, but by the end of the study (Day 35) all animals were free of abnormalities and showed an overall weight gain. Positive controls with 2-mercaptobenzothiazole in peanut oil confirmed the sensitivity of the test system.

CONCLUSION: There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test (100% notified chemical).

TEST FACILITY: Exxon (1999g)

7.7. Repeat dose toxicity

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
- Species/Strain: Rat/Crl:CDBR
- Route of Administration: Oral – gavage
- Exposure Information: Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 14 days
- Vehicle: Corn oil
- Remarks - Method: Neurotoxicity was evaluated by assessments of Functional Observational Battery (FOB) and motor activity, which is based on a photobeam activity system.

RESULTS

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

Mortality and Time to Death

All animals survived to scheduled study termination.

Clinical Observations

No clinical signs were judged to be treatment related. Single or low incidences of scabs, cores, dental abnormalities, dried red ocular discharge, red material seen on the snout, and alopecia were observed in one or more groups, including controls. Apparent differences were observed in the Functional Observational Battery (FOB) parameters and motor activity, but these were related to the findings in the pre-test measurements. All animals displayed weight gain with no biologically or statistically significant differences in mean body weight or mean food consumption between treated and control animals at any interval.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

There was a statistically significant increase compared to control for the mean prothrombin time of the 1000 mg/kg main study males and the mean haemoglobin of the 1000 mg/kg recovery males. However, the

increases were small and there were no corresponding microscopic changes in the tissues. No statistically significant differences from control were seen in the white blood cell differential counts, the serum and urine chemistry parameters. Additionally, the urine microscopy and dipstick data were unremarkable for both sexes at both intervals.

Effects in Organs

There was a statistically significant increase in the heart to body weight ratio in the 1000 mg/kg females compared with the controls. However, there were no microscopic findings related to this increase. The most frequently postmortem findings include alopecia, scabs, discoloured thymus, discoloured spleen, flaccid heart, dilated renal pelvis, and dental abnormalities. No treatment related microscopic changes were observed.

Remarks – Results

The differences in the mean prothrombin time, the mean haemoglobin and the heart to body weight ratio noted above were not considered biologically significant due to the lack of any corresponding histopathology findings. The clinical observations and postmortem findings were either scattered occurrences or found at similar incidence for all groups.

For the FOB and motor activity measures, differences in forelimb grip strength between the low and mid dose groups in the pretest interval, together with lethargic females (mid and high dose groups) and lethargic males (control and low dose groups) observed in the pretest interval and Week 4 respectively were suspected to be related to the sequential testing time for the pretest females and the Week 4 males with no conclusive statistical significance. A review of historical control motor activity data and the data collected in the normal fashion for this study revealed that the motor activity data for the 300 and 1000 mg/kg/day males at Week 4 was indicative of normal activity. On these bases, it was concluded that administration of the test substance did not produce alterations in FOB measures or motor activity at the doses investigated.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day, which is the highest dose tested in this study.

TEST FACILITY ExxonMobil (2001a)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD

	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 92/69/EEC B.14 Bacterial Reverse Mutation Test. Plate incorporation procedure.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102.
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: Test 1: 4, 12.5, 40, 125, 400 µg/plate. Test 2: 25, 50, 75, 100, 125 µg/plate. b) Without metabolic activation: Test 1: 4, 12.5, 40, 125, 400 µg/plate. Test 2: 25, 50, 75, 100, 125 µg/plate.
Vehicle	N,N-Dimethylformamide (DMF)
Remarks – Method	Two independent tests were conducted in triplicate. A vehicle solubility test indicated the solubility limit of 400 µg/plate in DMF.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>400	>400	≥125	Negative
Test 2	--	>125	≥125	Negative

Present				
Test 1	>400	>400	≥125	Negative
Test 2	--	>125	≥125	Negative

Remarks - Results The vehicle and positive controls responded appropriately.

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

TEST FACILITY Exxon (1999h)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line Chinese Hamster Ovary (CHO-WBL)
Metabolic Activation System S9 fraction from Aroclor 1254 induced rat liver.
Vehicle Acetone
Remarks - Method No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	1.25*, 4.0, 12.5*, 40, 125*, 250	3 h	19 h
Test 2	1.25*, 4.0, 12.5*, 40, 125*, 250	3 h	19 h & 43 h
Present			
Test 1	1.25*, 4.0, 12.5*, 40, 125*, 250	3 h	19 h
Test 2	1.25*, 4.0, 12.5*, 40, 125*, 250	3 h	19 h & 43 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>125	>250	≥12.5	Negative
Test 2	--	>250	≥12.5	Negative
Present				
Test 1	>125	>250	≥12.5	Negative
Test 2	--	>250	≥12.5	Negative

Remarks - Results There were no notable decreases (≥50% reduction compared to the vehicle control) in the mitotic index and cell confluency at any dose levels or harvest times in either the activated or non-activated cultures. The vehicle control percentages were <2% (which is within the 0-5% range of acceptance for the vehicle control) while those for the positive control groups were statistically significant higher than this for both the activated and non-activated series.

CONCLUSION The notified chemical was not clastogenic to CHO treated in vitro under the conditions of the test.

TEST FACILITY ExxonMobil (2001b)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test
Inoculum	Activated sewage sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	O_2 consumption
Remarks - Method	The test substance was evaluated in triplicate at a mean concentration of 52 mg/L. The percentage degradation of the test substance was calculated as: % deg = [(mg O_2 uptake by test sub. – mg O_2 uptake by blank) ÷ mg test sub. in vessel] × 100/ThOD, where ThOD = theoretical oxygen demand of the test substance calculated from elemental analysis.

RESULTS

Test substance		*Reference substance (Sodium benzoate)*	
Day	*% Degradation*	*Day*	*% Degradation*
1	0.16	1	6.5
7	0.00	7	94.5
21	0.00	21	97.1
28	0.00	28	97.6

Remarks - Results	The test is considered valid since it met the following OECD validity requirements 1) the degradation of sodium benzoate was in excess of 60% by day 14; and 2) the average cumulative oxygen consumed in the blank system was approximately 24 mg/L, ie not exceeding 60 mg/L. The degradation of the test substance after 1 and 28 days was essentially zero.
CONCLUSION	The notified chemical is not readily biodegradable.
TEST FACILITY	Exxon (1999i)

8.1.2. Bioaccumulation

The bioaccumulation of the notified chemical has not been determined. Bioaccumulation would not be expected due to the anticipated low environmental exposure of the notified chemical.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – semi-static (renewal) system.
Species	*Oncorhynchus mykiss* (rainbow trout)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	140-154 mg $CaCO_3$/L
Analytical Monitoring	Total organic carbon (TOC) analysis
Remarks – Method	This study was performed to determine the acute toxicity of the water accommodated fraction (WAF) of the test substance to rainbow trout. The loading levels were 1000, 500, 250, 125 and 62.5 mg/L. Individual treatment was prepared by adding the appropriate amount of the test

substance to 12 L of laboratory dilution water. The mixture was stirred for 24 h and allowed to cool and settle for 1 h. After settling the mixture appeared clear with the test substance at the surface. The WAF removed through the bottom of the vessel. The TOC values for the control ranged from 0.32-0.37, and for the WAFs between 0.33-1.7. Test solutions were renewed every 24 h by syphoning approx 80% and refilling with new WAF. There was no correlation with loading level and TOC. Water quality parameters of pH, temperature, O_2 content were within normal limits throughout the study.

RESULTS

Concentration mg/L Nominal Loading Level	*Number of Fish*	*Mortality*				
		2 h	*24 h*	*48 h*	*72 h*	*96 h*
0	10	0	0	0	0	0
62.5	10	0	0	0	0	0
125	10	0	0	1	0	0
250	10	0	0	0	0	0
500	10	0	0	0	0	0
1000	10	0	0	0	0	0

LC50	>1000 mg/L (WAF) at 96 hours
NOEC (or LOEC)	1000 mg/L (WAF) at 96 hours
Remarks – Results	One mortality was observed at 125 mg/L loading level on Day 2 of the study. Since no additional mortalities were observed at 125 mg/L, or higher loading levels, it is believed that this single mortality is unrelated to exposure to the test substance.

CONCLUSION The notified chemical is not toxic to fish up to the level of its water solubility.

TEST FACILITY Exxon (1999j)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD	EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – static test.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	140-154 mg $CaCO_3$/L
Analytical Monitoring	Total organic carbon (TOC) analysis
Remarks – Method	This study was performed to determine the acute toxicity of the water accommodated fraction (WAF) of the test substance to the daphnid. The loading rates were 1000, 500, 250, 125 and 62.5 mg/L. The WAFs were prepared in an analogous manner as for the fish study (above) except that only 2 L of solutions were prepared and the solutions were settled for 45 min not 1 h. After settling the mixture appeared clear with the test substance at the surface. The WAF removed through the bottom of the vessel and may have retained some insoluble substance. The TOC values for the control ranged from 0.47-0.49, and for the WAFs between 0.40-0.69. There was no correlation with loading level and TOC. Water quality parameters of pH, temperature, O_2 content were within normal limits throughout the study.

RESULTS

Concentration mg/L	*Number of D. magna*	*Number Immobilised*

Nominal Loading Level		*24 h*	*48 h*
0	20	0	0
62.5	20	0	0
125	20	0	0
250	20	0	7
500	20	0	14
1000	20	0	16

LC50 >1000 mg/L (WAF) at 24 hours
407 mg/L (WAF) at 48 hours

NOEC 125 mg/L (WAF) at 48 hours

Remarks - Results The apparent dose response curve with loading level is unusual given the absence of a correlation between loading level and TOC. The 48 h LC50 of 407 mg/L, with 95% confidence interval of 316 to 532 mg/L, is based on the natural log of the loading levels.

CONCLUSION The notified chemical shows some toxicity to daphnia at the concentrations present in the WAFs. It is possible that this was a physical effect from undissolved material.

TEST FACILITY Exxon (1999k)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species *Pseudokirchneriella subcapitata* (green algae)

Exposure Period 72 hours

Concentration Range Nominal: 1000, 500, 250, 125 and 62.5 mg/L

Auxiliary Solvent None

Water Hardness Not specified

Analytical Monitoring Total organic carbon (TOC) analysis

Remarks - Method Individual treatment was prepared in an analogous manner as for the fish study except that algal nutrient media was used in place of the laboratory dilution water. After settling the mixture appeared clear with the test substance at the surface. The WAF removed through the bottom of the vessel and this may have included some insolubles. The TOC values for the control ranged from 0.24-0.54, while for the WAFs the TOC values varied between 0.28-0.50. There was no correlation with loading level and TOC.

RESULTS

Biomass		*Growth*	
NOEC	*EL_b50*	*NOEC*	*EL_r50*
mg/L at 72 h	*mg/L 0-72 h*	*mg/L at 72 h*	*mg/L 0-72 h*
62.5	204	125	514

Remarks - Results Since a WAF of the test substance at a specific loading rate was tested, an EL50 (Effective Loading) was considered not an EC50 (Effect Concentration).

CONCLUSION The notified chemical shows some toxicity to algae at the concentrations present in the WAFs.

TEST FACILITY Exxon (1999l)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated domestic sewage sludge
Exposure Period	3 hours
Concentration Range	Nominal: 2.4, 5, 10, 25, 50 mg/L
Remarks – Method	Test was conducted using activated sludge obtained from sewage treatment plant in Annandale NJ USA. The reference material was 3,5-dichlorophenol.
RESULTS	
Remarks – Results	Varying levels of inhibition were observed for the test substance with the highest value, 9.88%, observed at the lowest concentration. An EC50 value was not calculated due to the poor linear correlation of the data. The scatter in the inhibition values is believed to be caused by the poor solubility of the test substance. The test substance is estimated to cause less than 10% inhibition of respiration in activated sludge. The EC50 of the reference substance was 10.3 mg/L, therefore confirming the suitability of the activated sludge.
CONCLUSION	The notified chemical is not expected to significantly inhibit microbial activity up to levels of 50 mg/L.
TEST FACILITY	Exxon (1999m)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is an additive in grease products, which are intended to have a long life and have been designed to last for the lifetime of the metal parts to which they have been applied. No environmental release of the greases is anticipated during transport and repackaging, except in the event of an accidental spill. Limited release of the notified chemical in greases could occur at end use during disposal of residues in used containers.

It is anticipated that spills and residues will be incinerated or sent to landfill. If it is assumed as a worst case that 1% of the notified chemical remains in containers, a maximum of 100 kg of the notified chemical could be disposed of in a diffuse manner in landfill or by incineration. Incineration would result in the production of oxides of carbon and nitrogen. With landfill disposal, the estimated logPow and low water solubility indicates that the notified chemical will be immobile in soil environments. While not readily biodegraded by sewage microorganisms, the notified chemical is likely to be slowly degraded in soil environments by soil microbes and abiotic processes.

As the notified chemical is to be used in long life greases, the majority of the notified chemical is expected to share the fate of the metal objects onto which it is adhering at the end of their useful lifetime. The majority of this is expected to be recycled with some being disposed of possible to landfill. In the metal recycling process the notified chemical will be incinerated producing the end combustion products as stated above.

9.1.2. Environment – effects assessment

The notified chemical is not toxic to fish up to the limit of its water solubility. Some toxicity is observed above the water solubility for both daphnia and algae. The notified substance is not expected to significantly inhibit microbial activity up to levels of 50 mg/L.

9.1.3. Environment – risk characterisation

Release of the notified chemical into the aquatic environment during normal use is not likely to occur. It is thus not possible to calculate a reasonable predicted environmental concentration (PEC). The notified chemical shows some toxicity to daphnia and algae. However, any environmental exposure of the notified chemical will be as a component of a hydrophobic grease, which will limit its solubility, and it is estimated the risk quotient (PEC/PNEC) should be very small.

Owing to its low water solubility and expected strong affinity to lipids, most of the notified chemical finding its way into the environment would ultimately end up in the soil rather than in the aquatic environment due to adsorption to particulate matter and later settling to sludge. Its low mobility in soil indicates the notified chemical is unlikely to represent a risk for contamination of ground or surface water.

The above considerations indicate a minimal risk to the environment when the notified chemical is used in the manner and levels indicated by the notifier.

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 chemical. In the event of an accident, spills will be removed in accord with the MSDS and government regulations.

During repackaging and cleaning procedures, dermal and ocular exposure will potentially occur due to drips and spills of the notified chemical, particularly, when workers connect or disconnect transfer hoses to a filling machine, meter or pump the imported grease into end use containers or cartridges. Workers may also make dermal contact with contaminated drum surfaces and residues of the notified chemical when scraping and placed them on the top of the next drum prior to attaching the pump for a next run. However, the packaging processes are generally semi-automated and will occur in an enclosed system, and worker intervention is not required unless the machine malfunctions or needs adjustment. The packaging operators generally receive adequate training in handling grease products, observe safe work practices and wear personal protective equipment such as gloves, chemical goggles, protective clothing, and respirators when required.

End users of the imported grease product may be exposed to notified chemical during re-lubricating the machine bearing or handling metal parts that have come into contact with the grease. Also, with the use of grease cartridges applied to the grease guns, there may be potential for high pressure injection of grease under the skin due to the rupture of pressurised lines. However, workers will wear impervious gloves and overalls, and observe industrial hygiene and safe work practices.

Overall, on the basis of the engineering controls, industrial hygiene, safe work practices and personal protective equipment, occupational exposure to the notified chemical would be limited.

9.2.2. Public health – exposure assessment

Members of the public may be exposed to the grease containing the notified chemical following transport accidents en route. Such accidents are unlikely. The repackaging and application of the grease will be conducted in an enclosed and controlled industrial environment. The well engineered processes and regulated disposal of wastes mean that public contact with the notified chemical through environmental releases is also unlikely. The potential for public exposure to the notified chemical therefore is assessed as negligible.

9.2.3. Human health - effects assessment

The notified chemical has a low acute oral and dermal toxicity in rats (LD50>2000 mg/kg bw). It is slightly irritating to the skin and eyes of the rabbit. It shows no sensitising activity up to 100% in a non-adjuvant study in guinea pigs. The NOAEL was established to be 1000 mg/kg bw/day, which is the highest dose tested in this study. The notified chemical was not mutagenic in a bacterial reverse mutation assay, and did not reveal any genotoxic potential in vitro.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002). However, repeated or prolonged skin contact with excessive lubricants and greases may result in skin irritation and/or dermatitis (oil acne or folliculitis) (NZDermNet, 2004).

9.2.4. Occupational health and safety – risk characterisation

The OHS risk presented by the notified chemical is expected to be low, given the low hazard of the chemical, the industrial hygiene, the good work practices and safety measures including use of appropriate personal protective equipment by workers.

The notified chemical may be present in formulations containing hazardous ingredients. If these formulations are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

9.2.5. Public health – risk characterisation

Given the notified chemical will only be used in industry and has low acute oral and dermal toxicity, the risk to public health is considered negligible.

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

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

As a comparison only, the classification of notified chemical 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.

The notified chemical is not classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) for both health and environmental hazards.

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 in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product Polyrex EM (containing 12% notified chemical) 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 product Polyrex EM (containing 12% notified chemical) 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

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in the final end use grease:
  - Enclosed and automated processes at the packaging and application sites, including use of semi-automated filling machines and metered pumps, enclosed cartridges and guns for grease application;
  - Adequate ventilation for the plant operators.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in the final end use grease:
  - Adequate training for staff in handling oils and lubricants;
  - Implementation of general health surveillance and monitoring programs as required.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in the lubricant additive package:
  - Industrial standard protective clothing and gloves;
  - Safety glasses with side-shields/chemical goggles;
  - Vapour respirators if required.

  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 chemical 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

- The following control measures should be implemented to minimise environmental exposure during transport, packaging and end use of the grease containing the notified chemical:
  - The notified chemical should not be disposed of into drains or onto the ground, but should be recycled or disposed of in accordance with State regulations. Do not allow spills or used lubricants to enter drains, sewers, water courses or soil.

Disposal

- The notified chemical should be disposed of to landfill or incineration.

Emergency procedures

- Spills/release of the notified chemical should be contained with absorbents or inert material (soil, sand, sawdust, vermiculite) and collected in sealable and labelled

containers for 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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