File No: NA/637

October 1999

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Chemical in PDN 1204

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Chemical in PDN 1204

1. APPLICANT

Infineum Australia Pty Ltd of 6 Riverside Quay SOUTHBANK VIC 3006 has submitted a standard notification statement in support of their application for an assessment certificate for the Chemical in PDN 1204.

2. IDENTITY OF THE CHEMICAL

Claims were made and accepted for the identity of PDN 1204 to be exempt from publication in the Full Public Report and the Summary Report. The data items were:

chemical name
molecular and structural formulae
molecular weight
spectral data
purity
non-hazardous impurity
details of the composition
exact import volume
details of customers, and
details of use

Chemical Abstracts Service (CAS) Registry No.:	not assigned
Trade Name:	PDN 1204, Paramar

3. PHYSICAL AND CHEMICAL PROPERTIES

The following physical and chemical properties are for the product PDN 1204, which contains the notified chemical. Several of the properties reflect those of the diluent in PDN 1204, mineral oil.

Appearance at 20°C and 101.3 kPa:	brown viscous liquid
Melting Point:	-15°C
Boiling Point:	320.6-722.5°C (represents boiling range temperature for mineral oil)
Specific Gravity:	1.1736 at 15.5°C
Vapour Pressure:	1.80×10^{-5} kPa at 35°C 2.70×10^{-5} kPa at 45°C 2.76×10^{-5} kPa at 55°C
Water Solubility:	< 1 mg/L at 20°C
Partition Co-efficient (n-octanol/water):	log P_{ow}< 0.3 (one component) log P_{ow} = 5.3-5.9 (2 components) log P_{ow} > 6 (at least 6 components) (see comments below)
Hydrolysis as a Function of pH:	not determined (see comments below)
Adsorption/Desorption:	(see comments below)
Dissociation Constant:	pK_a = 11.30 at 20°C
Flash Point:	180°C
Flammability Limits:	Upper Explosive Limit = 1.0% (finished lubricant) Lower Explosive Limit = 5.0% (finished lubricant)
Autoignition Temperature:	340°C (finished lubricant)
Explosive Properties:	not determined, but molecular structure does not indicate explosion hazard
Reactivity/Stability:	stable liquid

Fat Solubility: > 1 000 g/L at 37°C (see comments below)

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice. Full test reports were provided.

Concentrations of PDN 1204 in water were determined by the total organic carbon (TOC) analysis of the equilibrated solutions based on per cent carbon information.

Hydrolysis of the notified chemical was not determined. The notified chemical consists of a mixture of sparingly soluble calcium salts of organic anions, which when exposed to water would be expected to exist in a series equilibrium between the solid salts and the calcium cations and organic anions.

A partition coefficient test reported that PDN 1204 eluted several discrete chromatographic components when analysed by HPLC. The majority of these components were estimated to have log P_{OW} values greater than 5. At least one component had a log P_{OW} less than 0.3.

The adsorption/desorption behaviour of the notified chemical was investigated using OECD Test Guideline 106. A water soluble fraction (WSF) was prepared in a 0.01 M $CaCl_2$ solution. Triplicate samples of the WSF $CaCl_2$ solution were agitated with three soils (Colorado, Freehold and Snyder). Results show 12% adsorption to the high organic carbon content (2.44%) Colarado soil, 5.2% to the moderate organic carbon content < (2.01%) Snyder soil, and no adsorption to the low organic carbon (0.84%) Freehold soil. As the chemical is poorly soluble, TOC analysis was used to quantify the amount of organic carbon in the aqueous phases from the adsorption and desorption steps. This method measures all organic carbon in the system and is not specific to the notified chemical. These results are surprising, given the low water solubility of the notified chemical and the common ion effect in the $CaCl_2$ samples and the high partition coefficients of the components of the notified chemical. The low adsorption in the studies may reflect that the test was conducted on the WSF and therefore consist of the more polar fractions of the notified chemical which are less likely to adsorb. However, these results contrast with those obtained for the WSF of the closely related substance assessed as PDN 1266 (NA/630), which used a chemical specific HPLC method to analyse the samples and showed very high adsorption rates. Alternative explanations for the low adsorption in the current study are the presence of finely divided test material in the samples or organic carbon leached from the soils. Based on the low water solubility and the high partition coefficients of the components, they would be expected to adsorb strongly to soils and sediment.

Although PDN 1204 has a high fat solubility at least one minor component is poorly soluble in fat.

4. PURITY OF THE CHEMICAL

Degree of Purity: exempt information

Toxic or Hazardous Impurities: none

Additives/Adjuvants:

Chemical name:	mineral oil
Synonyms:	-
CAS No.:	64741-89-5

5. USE, VOLUME AND FORMULATION

The notified chemical is a component in an additive package (PDN 1204) to be used in lubricating oils for large marine diesel engines. PDN 1204 will be imported in bulk vessels or 205 L drums. Import volumes for the notified chemical are expected to be less than 200 tonnes per annum over the first five years.

The lubricating oils for end use will be formulated in Australia, with the notified chemical present at < 20% in the finished lubricant products.

6. OCCUPATIONAL EXPOSURE

Workers handling the notified chemical in Australia will include transport and storage workers, formulators, and end users.

PDN 1204 is a high boiling liquid so the principal route of exposure is expected to be by skin contact. Lubricating oils may generate oil mists so inhalational exposure is possible. The additive package (PDN 1204) containing the notified chemical is viscous thereby minimising its potential for aerosol formation.

Transport and storage
The notifier estimated that 2 workers would be involved in receiving the imported PDN 1204 at the dock and 1 to 2 workers transporting the notified chemical to the customer's formulation facilities. There would be approximately 12 truck deliveries per year.

Transport workers will also be involved in the delivery of finished lubricant products to commercial users. No exposure to the notified chemical is expected during transport and storage unless the package is breached.

Formulation
At formulation sites, lubricant processors blend PDN 1204 with mineral oil and other additives, in batches of 5 000-60 000 L, to form the finished lubricant. This final product is then repackaged into consumer size containers, generally 205 L drums or in bulk liquid trucks (10 000 L). After blending and packaging, the product containing the notified chemical is sold and transported to commercial user.

There are less than 20 formulation sites in Australia and there will be up to 4 workers involved in the process at each formulation site. The notifier estimated that less than 10 workers may come into contact with the notified chemical for each delivery per customer.

The formulation process is carried out using automatic equipment in an essentially closed system. Blending is carried out according to the following procedure:

- Connecting the additive container (with PDN 1204) to the transfer system via a flexible transfer hose.
- Pumping PDN 1204 into the blend tank via the transfer/stainless steel pipeline.
- Cleaning the container/transfer hose/pipeline and pump by flushing through with mineral base oil.
- Disconnecting the transfer hose.

Some leakage of PDN 1204 may occur during the connection and disconnection of transfer hoses. The amount is estimated by the notifier to be 1 kg per transfer. The lost material will be collected and recycled or properly disposed of. Workplace ventilation, including local exhaust ventilation, is provided to ensure that atmospheric concentrations are maintained as low as is practicable and below the NOHSC exposure standard of 5 mg/m^3 for mineral oil mist. In addition, workers will be protected with protective gloves, safety glasses, protective footwear and suitable industrial clothing.

The final products are automatically filled and sealed, so exposure is unlikely under normal circumstances. Skin contamination may occur in the event of overfilling of containers.

The notifier has reported that a comprehensive training session on the safe handling of chemicals for workers would be conducted whenever appropriate but at least once a year.

End users
End users will be potentially exposed to the notified chemical only during the addition of the lubricant product containing the notified chemical from the 205 L drums or 10 000 L bulk liquid truck into marine engines. Lubricants of this type are described as being direct injected into the combustion chambers of the marine engine. Detail of this process is not provided. Some minimal spillage may occur during the addition resulting in skin contamination. The notified chemical is presented < 20% in the finished products, so end-users are potentially exposed to smaller amounts of the chemical than formulation workers. The notified chemical is "consumed" (by thermal degradation) during use in the

diesel engines, so there will be no exposure to the notified chemical during collection and disposal of used oil from the engines.

7. PUBLIC EXPOSURE

PDN 1204 will be transported by truck to storage sites or to customer blending facilities. After blending and packaging, the finished oil containing the new product is sold and transported to commercial users only. Release to the atmosphere is unlikely to occur because of the low vapour pressure of PDN 1204.

The final product is a lubricating oil for diesel engine use only. The potential for public exposure to the notified chemical during transport, reformulation and use or from disposal is assessed as negligible.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier expects negligible environmental release of the notified chemical during product manufacturing. Fugitive emissions during transport and blending are considered by the notifier to be negligible due to the low vapour pressure of the substance. If spillages occur during the blending processes, they will be contained on-site and soaked up with absorbent material, *ie* sand or soil, before being transported off-site to an approved industrial facility for disposal by incineration. The drumming/re-packing of the finished lubricant product into consumer sized containers is essentially carried out in an automated filling line. Leakage from product transfer lines is expected to be very minimal, with it being collected then recycled or disposed of. On completion of the blending process, containers, transfer hoses, pipelines and pumps are cleaned by flushing through with mineral baseoil.

During use, the finished lubricant oils containing the notified chemical will be combusted along with the fuel. Hence, no used oil will be generated and release of the oil during use will be minimal.

The notifier estimates that an "empty" container has approximately 1.1% unused residues left inside. Therefore, up to 3 tonnes of the notified chemical (at maximum import volumes) may be present either for incineration as drum washings during reconditioning of the containers or for disposal to landfill.

Fate

The notified chemical will be used in diesel cylinder lubricants and will share their fate. Therefore, most spent oil will be combusted in the combustion chambers of the diesel

engines. Incineration products are expected to include oxides of carbon and sulfur, and calcium salts (in the ash).

A minor percentage will be released to the environment from spills and leaks, but this would be widely dispersed. Losses during transfer would be expected to remain bound to the soils or surfaces on which they fall.

The notified chemical was found to be not readily biodegradable (calculated as the ratio of the amount of CO_2 produced to the theoretical carbon dioxide ($ThCO_2$), expressed as a per cent). Biodegradation amounted to 25% at the end of the 28-day exposure to activated sludge from a domestic sewage treatment facility in the CO_2 Evolution (Modified Sturm Test) for ready biodegradability (OECD TG 301B). The notified chemical's inherent biodegradability was not measured but based on this result, the chemical is not expected to be persistent.

The potential for bioaccumulation was not determined. Due to the high partition coefficients of the components of the notified chemical (log P_{OW} > 5), low water solubility (0.001 mol/m^3) and high fat solubility, bioaccumulation of the notified chemical is possible (Connell 1989). However, biological membranes are not permeable to chemicals of very large molecular size (Gobas *et al.* 1986; Connell 1989). This combined with the low aquatic exposure would indicate that bioaccumulation of the notified chemical is not expected.

9. EVALUATION OF TOXICOLOGICAL DATA

The following toxicological studies were conducted on the product PDN 1204, which contains the notified chemical (in mineral oil), except for the eye irritation study, where a similar product, PDN 1266, was tested.

9.1 Acute Toxicity

Summary of the acute toxicity of PDN 1204.

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	(Frank, 1996a)
acute dermal toxicity	rabbit	LD_{50} > 2 000 mg/kg	(Frank, 1996b)
skin irritation	rabbit	not an irritant	(Frank, 1996c)
	human	very slight irritant	(Buehler, 1996)
eye irritation (PDN1266)	rabbit	slight irritant	(Frank, 1997)
skin sensitisation	guinea pig	moderate to strong sensitiser	(Frank, 1996d)
	human	not a sensitiser	(Buehler, 1997)

9.1.1 Oral Toxicity (Frank, 1996a)

Species/strain:	rat/Cr1:CD BR
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	oral (gavage)
Clinical observations:	2 females had anogenital staining at the 6 hour after treatment
Mortality:	nil
Morphological findings:	1 female had a dilated renal pelvis
Test method:	limit test, OECD TG 401 (Organisation for Economic Co-operation and Development, 1995-1996)
LD_{50}*:*	> 2 000 mg/kg
Result:	PDN 1204 was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Frank, 1996b)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	dermal application of 2 000 mg/kg (3 to 3.5 mL) under occlusive dressing for 24 hours
Clinical observations:	nil
Mortality:	nil
Morphological findings:	1 male had an unthrifty coat and 1 female had desquamation on the dose site

Draize scores (Draize, 1959):

Time after treatment (days)	***Animal #***									
	1	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***
Erythema										
1	3	3	3	3	3	3	3	3	3	3
3	2	1	2	2	2	1	1	2	2	1
Oedema										
1	2	1	2	1	2	2	1	2	2	2
3	0	0	1	1	1	0	0	1	1	0

[1] see Attachment 1 for Draize scales

Test method:	limit test, OECD TG 402 (Organisation for Economic Co-operation and Development, 1995-1996)
LD_{50}:	> 2 000 mg/kg
Comments:	Draize scores returned to zero by Day 7. transient erythema, oedema and subsequent atonia and/or desquamation were observed in all animals, but there were no significant postmortem findings.
Result:	PDN 1204 was of low dermal toxicity in rabbits

9.1.3 Inhalation Toxicity

Acute inhalation studies have not been performed for the notified chemical. The notifier claimed that the very low vapour pressure and the nature of its use indicate that inhalation exposure to the new chemical would not constitute a significant risk occupationally or to the general public.

9.1.4 Skin Irritation (Frank, 1996c)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	6 males
Observation period:	72 hours
Method of administration:	dermal application of 0.5 mL PDN 1204 to shoulder region under a semi-occlusive dressing

	for 4 hours
Draize scores	Draize scores for erythema and oedema were zero at 24, 48 and 72 hours for all the animals
Test method:	OECD TG 403 (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	PDN 1204 was not irritating to the skin of rabbits

9.1.5 Eye Irritation (Frank, 1997)

Eye irritation studies have not been performed for the notified chemical. However, an eye irritation study report is available for a similar substance, PDN 1266. On the MSDS for PDN 1204, it states that "eye contact will cause eye discomfort, but will not injure eye tissue".

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 males
Observation period:	3 days
Method of administration:	0.1 mL of test material applied as supplied into conjunctival sac of the right eye of each animal; the contralateral eye served as the control; animals were examined for eye lesions 1, 24, 48 and 72 hours after test substance application

Draize scores (Draize, 1959):

	Time after instillation											
Animal	***1 hour***			***1 day***			***2 days***			***3 days***		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	3	2	3	1	0	0	0	0	0	0	0	0
2	3	3	3	2	0	0	1	0	0	0	0	0
3	3	3	3	2	0	0	1	0	0	0	0	0

r redness *c* chemosis *d* discharge

Comment:	Draize scores for cornea and iris were zero up to 3 days in all animals; eye irritation was limited to the conjunctiva and was most prominent at the 1 hour observation time; all animals were free of irritation at the 72 hour observation time

Test method: OECD TG 405 [Organisation for Economic Cooperation and Development, 1987 #111]

Result: PDN 1266 was slightly irritating to the eyes of rabbits

9.1.6 Skin Sensitisation (Frank, 1996d)

Species/strain: guinea pig/Hartley Albino

Number of animals: 20 females (test group), 20 females (control group), 10 females (positive control)

Induction procedure: day 0 – PDN 1204 (0.4 mL, 100%) was applied to clipped left scapular area under a semi-occlusive dressing for 6 hours.

day 7 & 14 - same as day 0.

Challenge procedure: day 28 (challenge) – PDN 1204 (5% in peanut oil) was applied to the clipped right flank region under a semi-occlusive dressing for 6 hours

day 35 (rechallenge) – PDN 1204 (1% in peanut oil) was applied to the clipped left flank region under a semi-occlusive dressing for 6 hours

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
5%	**20/20	16/20	5/10	0/10
Rechallenge concentration				
1%	15/20	7/20	6/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Test method:	Buehler method, OECD TG 406 (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	PDN 1204 was a strong sensitiser to the skin of guinea pigs when challenged at 5% in peanut oil; when rechallenged with 1% PDN 1204 in peanut oil, the skin reactions were less marked but still indicative of a skin sensitising reaction.

9.2 Repeated Dose Toxicity (Trimmer, 1996)

Species/strain:	rat/Cr1: CD BR
Number/sex of animals:	5/sex/dose group
Method of administration:	oral (gavage)
Dose/Study duration::	group 1: 0 mg/kg/day (control) group 2: 100 mg/kg/day group 3: 300 mg/kg/day group 4: 1 000 mg/kg/day group 5: 1 000 mg/kg/day (satellite group) (vehicle: corn oil; animals were treated with PDN 1204 daily for 28 days; group 5 had a 14 day recovery after treatment)
Clinical observations:	no statistically significant differences in body weight gain or food consumption. sores and/or scabs in 3 group 3 rats, dried red ocular discharge in 1 group 5 female.
Clinical chemistry/Haematology	clinical chemistry revealed an increase in plasma chloride in group 4 females; in group 5, there were an increase in blood urea nitrogen and a decrease in phosphorus in males, and an increase in total bilirubin and a decrease in chloride in both males and females. haematological tests showed an increase in activated partial thromboplastin time in group 4 males; in group 5, there were a decrease in prothrombin time in males, an increase in prothrombin time in females, and an increase of

	large unclassified cells in both males and females.
Pathology:	there was an increase in mean liver-to-body weight ratios in group 3 and 4 males, liver-to-body weights returned to normal in recovery group 5. in group 5, there were a decrease in liver-to-body weight ratio in females in comparison with controls, a decrease in adrenal-to-brain weight ratio in comparison with group 4, and a decrease in liver-to-body weight ration in males in comparison with group 4.
Histopathology:	no significant treatment-related findings for tissues, including liver.
Test method:	OECD TG 407 (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	based on the relative liver weight gain, a no observable effect level (NOEL) of 100 mg/kg/day was established for the notified chemical; the no observable adverse effect level (NOAEL) for the notified chemical was considered to be 1 000 mg/kg/day, the highest dose.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Przygoda, 1996c)

Strains:	*Salmonella typhimurium* TA 98, TA 100, TA 1535, TA 1537 and TA 1538
Concentration range:	50 – 5 000 μg/plate (initial assay) and 12.5 – 500 μg/plate (repeat assay) in the presence or absence of metabolic activation (vehicle: tetrahydrofuran)
Test method:	OECD TG 471 (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	PDN 1204 was not mutagenic in the bacteria strains tested with or without metabolic activation.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse in vivo (Przygoda, 1996b)

Species/strain:	mouse/CD-1
Number and sex of animals:	5/sex/group
Doses:	group 1: 0 g/kg (control) group 2: 0.5 g/kg group 3: 1.0 g/kg group 4: 2.0 g/kg group 5: 20 mg/kg (cyclophosphamide, positive control)
Method of administration:	oral (gavage)
Test method:	OECD TG 475 (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	PDN 1204 did not produce an increase in micronuclei formation and did not induce cytotoxicity in the bone marrow in mice in comparison with the negative control, mutations were observed with the positive controls

9.3.3 Induction of Chromosome Aberrations in Cultured Chinese Hamster ovary (CHO) Cells in vitro (Przygoda, 1996a)

Species/strain:	Chinese hamster ovary (CHO) cells
Doses:	2, 4, 8, 16, 32 and 64 µg/mL in initial (16 hours) and repeat (16 and 40 hours) studies with and without S9 (vehicle: tetrahydrofuran)
Test method:	OECD TG 473 (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	PDN 1204 did not induce chromosomal aberrations in CHO cells while the vehicle and positive controls performed in an appropriate manner.

9.4 Human Studies

9.4.1 Primary Irritation in Humans (Single 24-Hour Application) (Buehler, 1996)

Subject:	human
Number/sex:	14 females and 1 male
Observation period:	24 hours
Method of administration:	test article A: 50% (w/w) in mineral oil test article B: 25% (w/w) in mineral oil test article C: 10% (w/w) in mineral oil test article D: mineral oil (control), test article E: 5% (w/v) sodium lauryl sulfate in water (positive control). each subject received a single dermal application of each test article to assigned skin site under a semi-occlusive patch for 24 hours.
Scores:	scores for erythema were recorded at 30 min and 24 hours after treatment, test article A exhibited no clinical irritation; test articles B, C and D each exhibited slightly transient erythema in 2 subjects; test article E exhibited strong irritation.
Test method:	Hill Top Research protocol
Result:	PDN 1204 was very slightly irritating to the skin of humans

Repeated Insult Patch Test (Modified Draize Procedure) (Buehler, 1997)

Subject:	human
Number:	pilot phase: 20 females and 9 males (15 females and 8 males completed the study) main phase: 84 females and 24 males (64 females and 18 males completed the study)
Induction procedure:	test article A: 50% (w/w) in mineral oil, test article B: mineral oil (control), test article C: 50% (w/w) in petrolatum, test article D: 50% (w/w) in petrolatum,

	test article E: petrolatum (control). each dermal exposure continued for 24 hours by contact under patch (semi-occlusive patches for test articles A and B, and occlusive patches for test articles C, D and E); 3 induction exposures per week for 3 weeks to the upper arm.
Challenge procedure:	challenge: contact patches for 24 hours on the opposite arm after 2 weeks rest period. rechallenge: applied test articles to a naive site to confirm reactions indicative of contact sensitization
Challenge outcome:	test articles A and B were tested in the pilot study; both test articles were non-irritating during the induction phase, and non-irritating and non-sensitising when challenged. test articles A, B, C, D and E were all essentially non-irritating with only a few mild erythema responses noted sporadically during the induction phase; subject No 114 had papules and scabbing to test article D following the 4th induction, another subject exhibited papules to test article C following the 7th induction; in both cases, no irritation were noted after the test sites changed. no positive controls were included in this study.
Test method:	modified Draize procedure
Result:	PDN 1204 was found to be non-sensitising and very slightly irritating in humans

9.5 Overall Assessment of Toxicological Data

PDN 1204 is of very low acute oral toxicity (LD_{50} > 2 000 mg/kg) in rats and low acute dermal toxicity (LD_{50} > 2 000 mg/kg) in rabbits. From the acute dermal irritation study, it was not found to be a skin irritant in rabbits. However, moderate dermal erythema and oedema were observed when applied at high dose (2 000 mg/kg) in the acute dermal toxicity study. The notified chemical was a positive skin sensitiser in guinea pigs

No eye irritation study was provided for the notified chemical, however, a study was available for a similar substance, PDN 1266. In the study PDN 1266 was slightly irritating to rabbit eyes, so it is concluded that PDN 1204 would also be a slight eye irritant.

The notifier provided two human studies for PDN 1204. A skin irritation study was performed with the notified chemical in mineral oil at the concentrations of 10, 25 and 50%. After applied for 24 hours on human skin, the notified chemical was not irritating. In a repeat insult patch test in human using a modified Draize procedure, the notified chemical (50%) in either mineral oil or petrolatum was found to be non-sensitising and only very slightly irritating.

In the 28 day oral repeat dose study with PDN 1204 in rats, the only treatment related effect was an increase of liver-to-body weight ratio in male rats at the doses of 300 and 1 000 mg/kg/day compared to the control group. However, there were no histopathological or clinical pathology changes to indicate liver toxicity, and the liver weight became comparable to the male control group following the recovery period. Based on the liver weight changes at the dose of 300 mg/kg/day, the NOEL for the notified chemical is 100 mg/kg/day. The NOAEL is considered to be 1 000 mg/kg/day due to the lack of other corroborative findings for the liver weight changes.

PDN 1204 was not mutagenic in a reverse mutation assay and was not clastogenic in CHO cells *in vitro*. The notified chemical tested negative in an *in vivo* micronucleus test in the mouse.

PDN 1204 was a strong sensitiser in guinea pigs, however, a well-conducted patch test in humans proved negative. Thus, the notified chemical is not classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a)

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out according to OECD Test Methods.

Species	*Test*	*Result(Nominal Concentrations of WAF[a])*	*Reference*
Rainbow trout *(Oncorhynchus mykiss)*	96 h Acute Toxicity Static renewal system [OECD TG 203]	LL_{50}[b] > 1 000 mg/L	Targia (1996a)
Water Flea (*Daphnia magna*)	48 h Acute Immobilisation Static system [OECD TG 202]	EL_{50}[c] > 1 000 mg/L	Targia (1996b)
Algal (*Selenastrum capricornutum*)	72 h Growth Inhibition Static system	E_RL_{50}[c] > 1 000 mg/L E_BL_{50}[c] > 1 000 mg/L NOEL[d] = 125 mg/L	Targia (1996c)

[a]Water accommodated fraction - see text below;
[b]LL_{50}: Lethal Loading;
[c]EL_{50}: Effect Loading.
[d]NOEL; No Observed Effect Loading

Due to the low water solubility of the notified chemical, the studies were performed to determine the toxicity of the water accommodated fraction (WAF). A 1 000 mg/L treatment was prepared and stirred for 24 hours. After settling for 1 hour, the WAF was removed and used as the treatment solution. In the fish and daphnia studies, total organic carbon (TOC) analysis indicated that the total organic carbon content of the WAFs was below the quantification limit of 1 ppm. Similarly in the algal study, dissolved organic carbon (DOC) analysis indicated that the dissolved organic carbon in the WAFs was below the detection limit of 1 ppm.

The notified chemical can be classed as non-toxic to rainbow trout, water fleas and algae, up to its limit of water solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Releases of the material to the environment are expected to be low as both product formulation and filling are performed under well controlled conditions and spills and other losses will be minimal (<2% of imported chemical).

The notified chemical will be injected directly into the combustion chamber. Hence, the ultimate fate of the majority of the material is expected to be via incineration of waste oil resulting in its destruction with production of non hazardous gases.

The environmental hazard from the notified chemical is small provided it is used in the manner indicated.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

PDN 1204 has low acute oral and dermal toxicity. It is expected to be a slight eye irritant. In guinea pigs, PDN 1204 was a skin sensitiser, however, in humans it was a very slight skin irritant but not a skin sensitiser. PDN 1204 did not cause adverse effects in a repeat dose toxicity test (NOAEL, 1 000 mg/kg/day) and was not mutagenic in *in vivo* and *in vitro* test systems. As the skin sensitising effects observed in animals could not be repeated in humans, the notified chemical is not classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a).

Acute inhalation studies have not been performed for the notified chemical. Although mineral oil mists may be hazardous, PDN 1204 has low vapour pressure and high viscosity, and is unlikely to be a significant inhalation hazard. Based on the human and animal toxicological data, slight skin irritation and possible skin sensitisation are the main acute toxicological hazards of the notified chemical.

The notifier indicated that no adverse health effects have been reported using this type of material which has been used in the occupational environment overseas for several decades.

Transport and storage workers
Transport and storage workers will be only be exposed to the notified chemical in the event of an accident or damage to the packaging. The occupational health risk to these workers is negligible.

Formulators
Dermal exposure to drips and spills, although expected to be low, is the predominant route of exposure for workers involved in formulation of the lubricant containing the notified chemical. Inhalation exposure is expected to be minimal because the notified chemical and the finished oil are viscous, therefore, have reduced potential to generate aerosols. In addition, the notified chemical has very low vapour pressure, so vapour accumulation in the workplace is not likely. Standard local exhaust systems exist in the formulation site, which would serve to further reduce inhalation exposure to a level below NOHSC exposure standard of 5 mg/m^3 for mineral oil mist. During formulating activities, the notifier recommends that workers wear protective gloves, safety glasses, protective footwear and suitable industrial clothing to minimise dermal exposure. Given the low hazard associated with the notified chemical, intermittent low level exposure to the notified chemical (considering the exposure control measures in place) and low concentration of the notified chemical in the oil, the occupational health risk posed to workers performing these tasks is considered to be low.

End users
The end users will add the product containing 6-16% the notified chemical into engines

only. Some exposure is expected. These workers are expected to wear personal protective equipment during work although this and the mode of injecting the lubricant oil into the marine engine were not specified in the submission. Their systemic health risk is considered to be low, however the possibility of topical effects cannot be excluded.

Public health
The notified chemical will be sold only to commercial users and will be used as a lubricant in marine diesel engines, for large deep ocean vessels. Based on the use pattern and its toxicological profile, PDN 1204 is considered not to pose a significant hazard to public health.

13. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994b).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

14. RECOMMENDATIONS

To minimise occupational exposure to PDN 1204, the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);
- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990);
- Impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion;

- A copy of the MSDS should be easily accessible to employees.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

Buehler E (1996) Evaluation of primary irritation in humans (single 24-hour application), Project No. 96-1134-70A, Hill Top Research Ltd, Cincinnati, USA.

Buehler E (1997) Repeated insult patch test , pilot and main study (modified Draize procedure), Project No. 96-1134-70B,C, Hill Top Research Ltd, Cincinnati, USA.

Connell DW (1989). "General characteristics of organic compounds which exhibit bioaccumulation". In Connell DW, (Ed) *Bioaccumulation of Xenobiotic Compounds*. CRC Press, Boca Raton, USA.

Draize JH (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49: 2-56.

Frank E (1996a) Acute dermal toxicity study in the rabbit, Project No. 141607, Exxon Biomedical Sciences Inc, New Jersey, USA.

Frank E (1996b) Acute oral toxicity study in the rat, Project No. 141602, Exxon Biomedical Sciences Inc, New Jersey, USA.

Frank E (1996c) Dermal sensitization study in the guinea pig (Buehler method), Project No. 141622, Exxon Biomedical Sciences Inc, New Jersey, USA.

Frank E (1996d) primary dermal irritation study in the rabbit, Project No. 141604, Exxon Biomedical Sciences Inc, New Jersey, USA.

Gobas FAPC, Opperhuizen A & Hutzinger O (1986). "Bioconcentration of hydrophobic chemicals in fish: relationship with membrane permeation". *Environmental Toxicology and Chemistry* 5: 637-646.

National Occupational Health and Safety Commission (1994a) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Canberra, Australian Government Publishing Service.

National Occupational Health and Safety Commission (1994b) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Canberra, Australian Government Publishing Service.

Organisation for Economic Co-operation and Development (1995-1996) OECD Guidelines for the Testing of Chemicals on CD-Rom. Paris, OECD.

Przygoda R (1996a) In vitro chromosomal aberration assay in Chinese hamster overy (CHO) cells, Project No. 141632, Exxon Biomedical Sciences Inc, New Jersey, USA.

Przygoda R (1996b) In vivo mammalian bone marrow micronucleus assay-oral gavage, Project No. 141630, Exxon Biomedical Sciences Inc, New Jersey, USA.

Przygoda R (1996c) Microbial mutagenesis in Salmonella mammalian microsome plate incorporation assay, Project No. 141625, Exxon Biomedical Sciences Inc, New Jersey, USA.

Standards Australia (1987) Australian Standard 2919-1987, Industrial Clothing. Sydney, Standards Association of Australia.

Standards Australia (1990) Australian Standard 3765.1-1990, Clothing for Protection against Hazardous Chemicals Part 1 Protection against General or Specific Chemicals. Sydney, Standards Association of Australia.

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Sydney, Standards Association of Australia.

Standards Australia/Standards New Zealand (1992) Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Sydney/Wellington, Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994) Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Sydney/Wellington, Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1998) AS/NZS 2161.2:1998 Occupational protective gloves, Part 2: General requirements, Standards Australia/Standards New Zealand.

Targia ME (1996a) Acute Fish Toxicity Test-rainbow Trout-Renewal. Report No. MRD 96-416, Study No. 141658. Environmental Toxicology and Chemistry laboratory, Exxon Biomedical Sciences Inc., East Millstone, New Jersey, USA. Unpublished.

Targia ME (1996b) *Daphnia* Acute Toxicity Test. Study No. 141642. Environmental Toxicology and Chemistry laboratory, Exxon Biomedical Sciences Inc., East Millstone, New Jersey, USA. Unpublished.

Targia ME (1996c) Algal Inhibition Test. Study No. 141667. Environmental Toxicology and Chemistry laboratory, Exxon Biomedical Sciences Inc., East Millstone, New Jersey, USA. Unpublished.

Trimmer G (1996) 28-Day repeated dose oral toxicity study in the rat with satelite recovery group, Project No. 141670, Exxon Biomedical Sciences Inc, New Jersey, USA.

Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe