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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Component of PDN 1266

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Component of PDN 1266

1. APPLICANT

Infineum Australia Ltd of Level 2, 6 Riverside Quay SOUTHBANK, MELBOURNE VIC 3006 has submitted a standard notification statement in support of their application for an assessment certificate for Component of PDN 1266.

2. IDENTITY OF THE CHEMICAL

Claims were made and accepted for the identity of Component of PDN 1266 to be exempt from publication in the Full Public Report. The data items were:

chemical name;
molecular and structural formulae;
molecular weight;
spectral data; and
methods of detection and determination – specific details enabling identification.

Chemical Abstracts Service (CAS) Registry No.:	none available
Trade Name:	PDN 1266
Method of Detection and Determination:	infrared spectroscopy, UV/Vis spectroscopy

A report with infrared and UV/Vis spectral data was submitted for the identification of the notified chemical.

3. PHYSICAL AND CHEMICAL PROPERTIES

The reported physical and chemical properties are those of the full product, PDN 1266, a mixture of mineral oil (39 %) and the notified chemical.

Appearance at 20°C and 101.3 kPa:	brown liquid

Boiling Point:	310-763 °C
Specific Gravity:	1.1413 g/mL @ 15.56 °C
Vapour Pressure:	7.9×10^{-7} kPa at 25°C 1.59×10^{-6} kPa at 35°C 3.12×10^{-6} kPa at 50°C
Water Solubility:	0.57 mg/L at 25°C
Partition Co-efficient (n-octanol/water):	log P_{ow} = 4 to > 6 for the range of components
Fat Solubility	> 1000 g/L, see comments below
Hydrolysis as a Function of pH:	not determined, see comments below
Adsorption/Desorption:	strongly adsorbed, see comments below
Dissociation Constant:	pK_a 7.70
Flash Point:	180 °C
Flammability Limits:	Upper Explosive Limit = 5.0 % Lower Explosive Limit = 1.0 % (for finished product)
Autoignition Temperature:	340 °C (for finished product)
Explosive Properties:	not explosive
Reactivity/Stability:	stable under ambient conditions

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines (European Economic Community, 1992; Organisation for Economic Co-operation and Development, 1995-1996) at facilities complying with OECD Principles of Good Laboratory Practice.

The notified substance is a component of a mixture of chemical species containing 39% mineral oil. The measured physico-chemical properties are those of the mixture, except as noted for the flammability properties, where the properties of the mineral oil impurity and diluent (in the final product) will be dominant and are thus reported.

The initial and final boiling points represent the boiling range temperature estimates for the

notified substance.

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

A partition coefficient test reported that the notified substance eluted several discrete chromatographic components when analysed by HPLC. The majority of these components of the notified substance were estimated to have log K_{OW} values ranging from 4 to greater than 6.

The adsorption/desorption behaviour of the notified chemical was investigated using OECD Test Guideline 106 (Organisation for Economic Cooperation and Development, 1993a). 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). The notified substance was not detected by HPLC (detection limit 7 ppm) in any samples of the aqueous phases for any soil, after centrifugation and extraction with dichloromethane. Hence, no calculation of adsorption data was performed. However, given the low water solubility of the notified substance, the high partition coefficients of the components of the notified substance and relatively high detection limit of the HPLC method, it is not surprising the notified substance was not detected in the extracts. 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 the notified substance has a high fat solubility, at least one of the components is poorly soluble in fat at low concentrations. However, increasing the concentration of the test substance resulted in its total dissolution in the synthetic fat at 37°C.

4. PURITY OF THE CHEMICAL

Degree of Purity:	notified chemical not isolated (57.6% (w/w) in mineral oil)
Toxic or Hazardous Impurities:	none

Non-hazardous Impurities
(> 1% by weight):

Chemical name:	phenol, C_{14} – C_{18} derivatives
Weight percentage:	2.5 %
CAS No.:	none

Additives/Adjuvants:

Chemical name:	mineral oil
CAS No.:	64741-89-5
Weight percentage:	39 %

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It will be imported in bulk vessels or 205 L drums as a component (20-50% (w/w)) of a lubricant additive package. Import volumes for the notified chemical are expected to be 150 tonnes per annum over the first five years with the possibility of increasing to 250 tonnes per annum.

The notified substance is a component of a diesel engine lubricating oil additive package. It is to be used as a detergent component in diesel engine oil for use in deep ocean going vessels and will be present in a concentration range of 1 to 10% (w/w) in the finished lubricant products.

Blending of the additive package (containing the notified substance) takes place at the customer's facility. The customers are existing formulators of lubricating fluids. The notifier estimates that the blending of the lubricants may take place at up to 17 sites across Australia. Lubricant processors blend the additive package with mineral oil and other additives, in batches of 5 000-60 000 L, to form the finished lubricant. This product is then repackaged into consumer size containers, generally in 205 L drums or in bulk liquid trucks (10 000 L). After blending and packaging, the finished oil containing the notified chemical is sold and transported to commercial users.

6. OCCUPATIONAL EXPOSURE

Exposure to waterside and transport workers is unlikely except in case of a spill. It is estimated that two workers will be involved in receiving delivery at the dock and up to two in transport to the blending facilities.

Repackaging
The notified chemical will be reformulated in Australia, by blending with engine oil, by the customers who are existing formulators of lubricating fluids. The notified chemical has a very low vapour pressure and, as a mineral oil based product, a high viscosity, minimising the possibility of vapour and aerosol formation. Therefore the main route of exposure would be expected to be via skin contact.

The notifier indicates that the blending and repackaging processes will be completely automated, with worker involvement limited to connecting and disconnecting a flexible transfer hose to the shipping container, and packaging sealed 205 L drums of the end product. Transfer of the completed product to 10 000 L bulk liquid trucks is also expected. Dermal exposure to drips during the connection and disconnection of the transfer hoses may occur. It is estimated that one to four workers will be involved in the blending process.

The notifier indicates that the workers involved in the reformulation operations for this product will wear protective gloves, glasses, footwear and industrial clothing complying with the relevant Australian Standards (Standards Australia, 1990; Standards Australia, 1994; Standards Australia/Standards New Zealand, 1994; Standards Australia/Standards New Zealand, 1998). The notifier also indicates that the operations would be conducted with adequate workplace ventilation, including local exhaust ventilation.

End Use
The notified chemical, as a component comprising 1 to 10 % (w/w) of a finished lubricant, will only be provided to commercial users in the marine industry. The transfer of the finished lubricant from the commercial container (either 205 L containers or 10,000 L bulk liquid trucks) into the sealed marine diesel engine crankcase, and the removal of used oil for disposal, present opportunities for dermal exposure by marine engine mechanics. The notifier has suggested that lubricating fluids in such systems are however not frequently changed. At high temperatures, the notified chemical may degrade to emit vapours of toxic sulphur compounds. Therefore end users could be exposed by inhalation to toxic degradation products after the oil has been used at elevated temperatures.

Disposal
Disposal of waste oil is expected to be either through burning with fuel oil on board ship, or by disposal at port facilities for recycling, re-refining or burning by commercial contractors. Dermal exposure to drips is possible as the oil is transferred to the disposal facility tanks and also within the disposal facility. Exposure to toxic decomposition products is also possible for the disposal workers, as detailed above.

7. PUBLIC EXPOSURE

As the notified chemical is intended to be used in an industrial environment during all phases of its life cycle, including transport, reformulation, use and disposal, the potential for public exposure to the notified chemical is considered to be negligible.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier expects negligible environmental release of the notified substance during product manufacture. Fugitive emissions during transport and blending are considered by the notifier to be negligible due to the very 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, i.e. 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 carried out in an automated filling line. Leakage from product transfer lines is expected to be minimal; it will be collected for recycling or disposal. On completion of the blending process, containers, transfer hoses, pipelines and pumps are cleaned by flushing through with mineral base oil.

During use, the finished lubricant oils containing the notified substance are generally considered to be contained in the crankcase of the diesel engines until the lubricant is changed. Some of the notified substance will be combusted during use. The notifier estimates that >98% of used oil will be disposed of correctly either in Australian or foreign ports. Collected used lubricants will be either recycled, cleaned or burnt (as fuel oil including on board ship) or consigned to landfill at an approved industrial facility. It should be noted that the community is reluctant to use re-refined oils and thus the recycled product usually ends up on the fuel oil market (Snow, 1997).

The remaining <2% (<5 tonnes) may potentially be released to the environment in an extremely disperse manner. Release of the lubricants to the environment may occur due to engine leaks and during engine oil changes. It is anticipated that the majority of these releases would take place onshore during the transfer of engine oils containing the notified substances to and from the ships. Additionally, it is expected that engine leaks would be contained in the engine room of the ship. Hence, exposure of the notified substance to the aquatic compartment is expected to be extremely limited.

The notifier estimates that an "empty" container retains approximately 1.1% unused residues. Therefore, up to 2.75 tonnes of the notified substance (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 substance will be used in diesel engine lubricants and will share their fate. Therefore, most spent oil will be combusted either directly as used or as re-refined oil (Snow, 1997). Incineration products are expected to include oxides of carbon and sulfur, and inorganic salts (in the ash).

A minor component 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 substance was not readily biodegradable (calculated as the ratio of the amount of CO_2 produced to the theoretical carbon dioxide ($ThCO_2$), expressed as per cent). Biodegradation amounted to 24% 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 (Sinko, 1997) according to OECD Guideline 301B (Organisation for Economic Cooperation and Development, 1993b). The inherent biodegradability of the notified substance was not measured but based on the biodegradation result it would not be expected to be persistent.

The potential for bioaccumulation was not determined. Due to the high partition coefficients of the components of PDN 1266 (log K_{OW} >4), low water solubility (0.00058 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 (Connell, 1989; Gobas et al., 1986). This combined with the low aquatic exposure indicates that bioaccumulation of the notified substance is not expected.

9. EVALUATION OF TOXICOLOGICAL DATA

The notified chemical is manufactured in mineral oil and is never isolated; thus the test material is a mixture of chemical species containing 39 % mineral oil. The toxicological properties are those of the mixture.

9.1 Acute Toxicity

Summary of the acute toxicity of PDN 1266

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2000 mg/kg	(Frank, 1997c)
acute dermal toxicity	rat	LD_{50} > 2000 mg/kg	(Frank, 1997b)
skin irritation	rabbit	non-irritating	(Frank, 1997f)
eye irritation	rabbit	mild irritant	(Frank, 1997e)
skin sensitisation	guinea pig	non-sensitising	(Frank, 1997d)

9.1.1 Oral Toxicity (Frank, 1997c)

Species/strain:	rat/Crl:CDBR
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage, dose level 2000 mg/kg, dose volume 1.79 mL/kg; test material used as received
Mortality:	there were no deaths during the study
Clinical observations:	no clinical signs of toxicity were observed during the study
Morphological findings:	no gross abnormalities were observed on day 14
Test method:	limit test similar to OECD guideline 401 (Organisation for Economic Cooperation and Development, 1987c)
LD_{50}:	> 2000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Frank, 1997b)

Species/strain:	rat/Crl:CDBR
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	semi-occluded patch; 24 hour exposure dose level: 2000 mg/kg; dose volume: 1.79 mL/kg; test material used as supplied
Mortality:	there were no deaths during the study
Clinical observations:	no clinical signs of toxicity were observed during the study
Morphological findings:	no gross abnormalities were observed on day 14
Test method:	limit test similar to OECD guideline 402

	(Organisation for Economic Cooperation and Development, 1987a)
LD_{50}:	> 2000 mg/kg
Result:	the notified chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

The notifier claims that the very low vapour pressure of PDN 1266 and the nature of its use indicate that inhalation exposure would not be a significant risk occupationally or for the general public, and for this reason acute inhalation studies have not been performed.

9.1.4 Skin Irritation (Frank, 1997f)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 males
Observation period:	3 days
Method of administration:	0.5 mL of test material as supplied was applied to clipped intact skin of the dorsal flank and secured under a gauze patch for 4 hours; at the end of this time, residual material was removed with peanut oil and paper towels; animals were examined for skin lesions 1, 24, 48 and 72 hours following application of the test substance
Test method:	similar to OECD guideline 404 (Organisation for Economic Cooperation and Development, 1992a)
Comment	very slight erythema was noted in one animal at the 1 hour observation time; all animals were free of erythema, oedema or other signs of dermal irritation at the 24, 48 and 72 hour observation times
Result:	the notified chemical was not irritating to the skin of rabbits

9.1.5 Eye Irritation (Frank, 1997e)

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) of unirrigated eyes:

	Time after instillation											
Animal	***1 hour***			***1 day***			***2 days***			***3 days***		
Cornea	***o***	***a***		***o***	***a***		***o***	***a***		***o***	***a***	
1	0	0		0	0		0	0		0	0	
2	0	0		0	0		0	0		0	0	
3	0	0		0	0		0	0		0	0	
Iris												
1	0			0			0			0		
2	0			0			0			0		
3	0			0			0			0		
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

[1] see Attachment 1 for Draize scales
o opacity *a* area *r* redness *c* chemosis *d* discharge

Comment: 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: similar to OECD guideline 405 (Organisation for

Economic Cooperation and Development, 1987b)

Result: the notified chemical was mildly irritating to the eyes of rabbits

9.1.6 Skin Sensitisation (Buehler method) (Frank, 1997d)

Species/strain: guinea pig/Hartley

Number of animals: 20 test;
20 irritation control;
10 positive control

Induction procedure: Days 0, 7 and 14:
test animals – occluded application of neat test material (0.4 mL) to a clipped area of the left shoulder for 6 hours; the residue was removed with peanut oil and paper towel
positive control – occluded application of 50 % 2-mercaptobenzothiazole (MBT) in peanut oil (0.4 mL), similar to the treatment of the test animals

Challenge procedure: Day 28
test animals – neat test material (0.4 mL) was applied topically via fastened, occluded chambers, to a clipped area of the right flank for 6 hours; the residue was removed with peanut oil and paper towel
irritation control – same procedure as that for test animals for 10 of the irritation control group

dermal responses were evaluated after 24 and 48 hours

Day 29
positive control – occluded application of 20 % MBT in peanut oil (0.4 mL) similar to the treatment of the test animals

Day 35
test animals - neat test material (0.4 mL) was applied topically via fastened, occluded chambers, to a clipped area of the left flank for 6 hours; the residue was removed with peanut oil and paper towel

irritation control – same procedure as that for test animals for 10 of the irritation control group

dermal responses were evaluated after 24 and 48 hours

Challenge outcome:

	Test animals		***Control animals (Irritation)***	
Concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
Challenge 100%	**13/20	6/20	5/10	1/10
Rechallenge 100%	2/20	0/20	3/10	0/10

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

Test method: similar to OECD guideline 406 (Organisation for Economic Cooperation and Development, 1992c)

Comment dermal responses following challenge dosing were equivocal and thus rechallenge dosing was performed; the test material did not show clear evidence of contact sensitisation following rechallenge; on the basis of the results of the rechallenge the test material was not considered positive for skin sensitisation; the positive control material produced evidence of sensitisation indicating that the test system responded appropriately

Result: the notified chemical was not sensitising to the skin of guinea pigs under the conditions of this test

9.2 Repeated Dose Toxicity (Frank, 1997a)

Species/strain: rat/Crl:CDBR

Number/sex of animals: 5/sex control group;
5/sex each treatment group;
5/sex recovery group

Method of administration: dermal, test material applied to a clipped, unabraded site on the back of each animal (approximately 10% of total body surface) and

	held under semi-occlusive dressing and covered with a body wrap for 6 hours; residual test material was removed with peanut oil and paper towels
Dose/Study duration::	100, 300 and 1000 mg/kg applied daily for 28 consecutive days recovery group animals were dosed with 1000 mg/kg daily for 28 consecutive days, then allowed to recover for 14 days
Clinical observations:	no deaths were observed; no clinical signs of toxicity observed; no significant differences in mean food consumption or bodyweight gain
Dermal observations:	males: no oedema or erythema females: very slight transient erythema was observed in animals of the mid (2) and high dose (1) groups, and in the recovery group (3), all within the first 14 days; well defined erythema was observed in one animal of the high dose group on Day 7; all animals were free of irritation for the remainder of the study
Clinical chemistry/Haematology	treatment phase – no significant differences in haematological parameters; no significant differences in serum chemistry other than a significant increase in triglycerides of the females of the 1000 mg/kg dose group; no equivalent findings were observed for the males of this dose group, or for either the males or females of the recovery group at 28 days; wide variations in individual animal results over all groups were observed recovery phase – statistically significant decreases in mean corpuscular volume and mean absolute neutrophils for males and in mean percentage monocytes for females; statistically significant increases in mean percentage lymphocytes for all animals, in mean absolute lymphocytes for females and in mean corpuscular haemoglobin concentration for males; these were not considered to be related to the test material in the absence of positive results at the termination of the main study and other corroborating clinical or histopathological effects

	there were also statistically significant changes in serum chemistry for the males in this group; increases in mean sodium, potassium, glucose and total protein and a decrease in phosphorus; all values remained within the normal range
Organ Weights	treatment phase – statistically significant increases in mean absolute and mean relative kidney to body weights for 100 mg/kg females and statistically significant decrease in mean relative liver to brain weight for 300mg/kg males; in the absence of clear dose response these were not considered significant recovery phase – statistically significant decreases in mean relative brain to body weight and testes to body weight for males and liver to body weight for females and a statistically significant increase in mean relative kidney to brain weight for males, compared with the 1000 mg/kg group at the end of the main study, and a statistically significant decrease in mean relative liver to body weight for males compared to the controls; the differences were small (<12%) and in the absence of similar findings in the main study or corroborating clinical or histopathological effects were considered spurious and unrelated to the treatment
Histopathology:	treatment phase - no macroscopic or microscopic changes in any of the tissues, including the dermal application site, or organs examined, to indicate any systemic toxicity or local irritating effect; skin lesions and dermal inflammatory cell infiltration were observed in all animals and were attributed to the repeated shaving and wrapping of the skin during the dosing procedure recovery phase - no macroscopic or microscopic changes in any of the tissues or organs examined to indicate any systemic toxicity
Test method:	similar to OECD guidelines 410 (Organisation for Economic Cooperation and Development, 1981)
Result:	the notified chemical did not elicit signs of systemic toxicity following repeat dermal application; a No

	Observed Effect Level (NOEL) was established at 1000 mg/kg

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Przygoda, 1997a)

Strains:	*Salmonella typhimurium*: TA98, TA100, TA1535, TA1537, TA1538
Concentration range:	initial assay 0, 100, 500, 1000, 2500, 5000 µg/plate repeat assay 0, 1000, 2000, 3000, 4000, 5000 µg/plate
Metabolic Activation System:	rat liver S9 fraction from animals pretreated with Aroclor 1254
Test method:	similar to OECD guideline 471 (Organisation for Economic Cooperation and Development, 1983c)
Positive controls	9-aminoacridine (9AA) 2.5 µg/plate – all strains with S9 2-aminoanthracene (2AA) 100 µg/plate – TA 1537, without S9 N-methyl-N-nitro-N-nitrosoguanidine (MNNG) 10 µg/plate – TA100, TA1535 without S9 2-nitrofluorene (2NF) 5 µg/plate – TA98, TA1538 without S9
Comment	toxic effects were observed at 5000 µg/plate in the initial assay and at 4000 and 5000 µg/plate in the repeat assay; closer dose intervals were chosen in the repeat assay to confirm the initial negative result; the positive controls produced clear positive results indicating that the test system responded appropriately
Result:	the notified chemical was not considered mutagenic in the bacterial strains tested in the absence or presence of metabolic activation provided by rat liver S9 fraction

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Przygoda, 1997c)

Species/strain:	mouse/CD-1
Number and sex of animals:	5/sex/dose
Doses:	test material 500, 1000, 2000 mg/kg positive control (cyclophosphamide) 20 mg/kg
Method of administration:	gavage; test and positive controls administered as three treatments at 24 hour intervals
Test method:	similar to OECD guideline 474 (Organisation for Economic Cooperation and Development, 1983b)
Comment:	there was no significant difference in micronuclei formation in any of the test animals; the positive control induced a statistically significant increase indicating that the test system responded in an appropriate manner
Result:	the notified chemical did not induce a significant increase in micronucleated polychromatic erythrocytes in the bone marrow cells of the mouse

9.3.3 Chromosomal Aberrations in Chinese Hamster Ovary (CHO) Cells *In Vitro* (Przygoda, 1997b)

Cells:	Chinese Hamster Ovary (CHO)
Doses:	test material 80, 160, 240, 320 µg/mL with metabolic activation 40, 80, 160 µg/mL without metabolic activation positive controls: N-methyl-N-nitro-N-nitrosoguanidine (MNNG) 0.6 µg/mL (for cells treated without metabolic activation); 7,12-dimethybenz[a]anthracene (DMBA) 10 µg/mL (for cells treated with metabolic activation)
Metabolic Activation System:	rat liver S9 fraction from animals pretreated with Aroclor 1254
Treatment Regime:	test material or positive controls added to cell

	cultures in serum free medium for 3 hour incubation with or without metabolic exogenous activation system; the cells were then washed and incubated in fresh complete medium for a total of 16 or 40 hours ; colcemid was added 2-3 hours before harvest to arrest cells in metaphase;
Test method:	similar to OECD test guideline 473 (Organisation for Economic Cooperation and Development, 1983a)
Result:	the notified chemical did not induce a significant increase in chromosomal aberrations in Chinese hamster ovary cells *in vitro* with or without metabolic activation

9.4 Overall Assessment of Toxicological Data

The notified chemical is contained within a mixture of a number of different chemical species, including a high percentage of mineral oil. It is not possible to isolate the notified chemical, consequently it is not possible to determine which components are responsible for the observed toxicological effects. The toxicological assessment assumes that the toxicity of the notified chemical reflects that of the test substance.

The acute oral toxicity in rats is very low (LD_{50}>2000 mg/kg) and the acute dermal toxicity in rats is low (LD_{50}>2000 mg/kg).

The notified chemical is not irritating to rabbit skin.

The notified chemical did not elicit corneal or iridal effects in rabbit eyes, though conjunctival effects were present for 48 hours and were most severe at the one hour observation time. The mean scores for conjunctival effects were below the threshold for classification as irritating to eyes according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a).

In a non-adjuvant skin sensitisation study in guinea pigs, the challenge dose gave equivocal responses, whereas the rechallenge dose provided no clear evidence of skin sensitisation. On the basis of the rechallenge results, and for the purposes of this assessment, it is accepted that the notified chemical is not a skin sensitiser.

In a 28 day repeat dose dermal toxicity study in the rat, no treatment related systemic toxicity was observed for any of the doses tested, up to 1000 mg/kg/day. The observed anomalies in recovery group animals were identified as spurious and considered not to be related to the administration of the test material. A NOEL of 1000 mg/kg was established.

The notified chemical was not found to be mutagenic in bacteria and did not induce an increase in micronuclei in the *in vivo* mouse micronucleus assay. No clastogenic effects were found in the *in vitro* Chinese hamster ovary cell cytogenic assay.

Based on the data provided, the notified chemical would not be classified as hazardous according to the 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. (Organisation for Economic Cooperation and Development, 1984; Organisation for Economic Cooperation and Development, 1992b).

Test	*Species*	*Results (Nominal Concentrations of WAF[a])*	*Reference*
acute toxicity	rainbow trout	LL_{50}[b] > 1,000 mg/L	(Febbo, 1997a)
acute toxicity	*Daphnia magna*	EL_{50}[c] > 1,000 mg/L	(Febbo, 1997b)

[a]Water accommodated fraction - see text below; [b]LL_{50}: Lethal Loading; [c]EL_{50}: Effect Loading

Due to the low water solubility of the notified substance, 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. The WAFs were slightly cloudy.

The notified substance can be classed as non-toxic to rainbow trout and water fleas, up to its limit of solubility (the WAF).

No study on the toxicity of the notified substance to algae has been submitted by the notifier. The notifier justifies this omission on the grounds that the substance exhibits low toxicity to other aquatic organisms and mammals. This is acceptable as a component of the notified substance for which the 1,000 mg/L WAF was not toxic to algae has been previously assessed.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Environmental releases of the material are expected to be low as both product formulation and crankcase filling are performed under well controlled conditions. Spills and other losses will be minimal (<2% of imported chemical).
In excess of 98 percent of used oil containing the notified substance will be disposed of

appropriately, namely recycled, cleaned or burnt (as fuel oil including on board ship) or consigned to landfill at an approved industrial facility. It is noted that the community is reluctant to use re-refined oils and they usually end up on the fuel oil market (Snow, 1997). Hence, the ultimate fate of the majority of the material is expected to be 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

The notified chemical is of low acute oral and dermal toxicity, is not irritating to skin and is not sensitising to animal skin. The mean scores for eye irritation were below the threshold for classification as irritating to eyes according to the NOHSC Approved Criteria (National Occupational Health and Safety Commission, 1994a). The notified chemical did not cause systemic toxicity in a repeat dose toxicity test and was not mutagenic in *in vivo* and *in vitro* test systems. Based on the results of toxicity tests, PDN 1266 would not be classified as hazardous according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a).

The notified chemical will be imported in bulk vessels or 205 L drums as component (20-50% (w/w)) of a lubricant additive package. The additive package will be reformulated in Australia, by blending with engine oil. The final product is then repackaged into containers for transport to the industrial end user, generally 205 L drums or bulk liquid trucks (10 000 L).

Dermal exposure to drips and spills would be the predominant route of exposure for workers involved in repackaging the imported oil containing the notified chemical, in the end use applications and during disposal. 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 air is not likely. Standard local exhaust systems exist in repackaging facilities, which serve to further reduce inhalation exposure. During repackaging activities the notifier recommends that workers wear personal protective equipment, to minimise skin contact and to protect the eyes. Given the low toxic hazard associated with the notified chemical, the anticipated intermittent low level exposure to the notified chemical and low concentration of the notified chemical in the oil (up to 10 %), the occupational health risk posed to workers performing these tasks is considered to be low.

The notified chemical degrades thermally to emit toxic fumes, so there is some risk of acute health effects by inhalation when users are handling or disposing of previously heated oil. Respiratory protection may be required.

In addition, the notified chemical will be used in the presence of mineral oil, which may be slightly irritating to the skin in the short term and cause dermatitis after chronic exposure.

Mineral oil mists may cause respiratory irritation at high concentrations. The conditions of use of the notified chemical do not indicate that mineral oil mists would be generated. Therefore inhalation or skin contact is unlikely, however, if mists are generated, employers should ensure that the NOHSC exposure standard for mineral oil mist of 5 mg/m^3 TWA (National Occupational Health and Safety Commission, 1995) is observed.

Under normal working conditions, waterside, transport and storage workers are unlikely to be exposed to the notified chemical and the occupational health risk posed to these workers is considered very low.

As the notified chemical is intended to be used in an industrial environment during all phases of its life cycle, including transport, reformulation, use and disposal, the potential for public exposure to the notified chemical is considered to be negligible.

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 1266 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 3765.2 (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 be put into containers for disposal;

- Good personal hygiene should be practiced to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.
- If oil mists are generated, employers should ensure that the NOHSC exposure standard for mineral oil mist (5 mg/m^3 TWA) is not exceeded in the workplace.

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.

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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