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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

C9417

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Infineum Australia Pty Ltd (ABN 24084881863)
2/6 Riverside Quay
SOUTHBANK VIC 3006

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, CAS No., molecular and structural formulae, molecular weight, spectral data, purity, precise concentration in the additive package and final product and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: vapour pressure, water solubility, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, particle size, flammability, autoignition temperature, skin irritation, skin sensitisation, induction of point mutations and chromosome damage.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
None.

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
C9417.

MARKETING NAME(S)
The notified chemical will be imported as a component of lubricant additive packages P5314, P5414A, D3413 and D3426.

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Infrared (IR) spectroscopy.
Remarks	An IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
High.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)
None.

ADDITIVES/ADJUVANTS
The notified chemical as manufactured contains highly refined mineral oil.

The imported lubricant additive packages will contain < 20% (w/w) of the notified chemical.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
As a component of lubricant additive packages in bulk containers or 205 L drums.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 1000	< 1000	< 1000	< 1000	< 1000

USE
Lubricant additive.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Unknown.

IDENTITY OF MANUFACTURER/RECIPIENTS
Notifier.

TRANSPORTATION AND PACKAGING
Bulk vessels or 205 L drums.

5.2. Operation Description

The lubricant additive packages containing the notified chemical will be transported to customer blending facilities and transferred to bulk storage tanks or retained in steel drums. The additive package is pumped to a blending tank together with other addenda and mineral oil or transmission fluid. After blending the finished product which contains < 2% notified chemical is automatically packed into containers of 2 – 200 L capacity.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport	3 - 4	Up to 8 hours per day	60 days per year
Lubricant blending	1 – 4 per site (10 sites)	1 hour per week	48 hours per year
Mechanics	Hundreds	Up to 8 hours per day	Up to 230 days per year

Exposure Details
Inhalation exposure is unlikely as the notified chemical has a low vapour pressure. Exposure to oil mists will be controlled by local exhaust ventilation. Minor leakage is expected while connecting and disconnecting transfer hoses and cleaning out additive by flushing through with mineral oil. The losses are collected and recycled or sent for disposal. The filling lines will be automatic and exposure of packing operators should be minimal.

Mechanics may experience skin and eye contact while changing oil and handling car parts partially coated with oil. The oil can remain in contact with the skin or eye for an extended period.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The most likely release of the notified chemical at blending sites or during transport would be from accidental spillage. Losses during transfer and blending are expected to be low as a closed system will be used and any spillage will be contained and absorbed with earth or sand before disposal at an approved industrial facility.

The notifier estimates that about 1% of residues remain inside "empty" containers. If 1000 tonnes of the new chemical are imported per year, then about 10 tonnes will be disposed of by incineration as drum washings during the reconditioning of the containers.

RELEASE OF CHEMICAL FROM USE

The only end use of the additive package containing the new chemical is expected to be engine oil and transmission fluids where the new chemical will be < 2% of the finished lubricant. There may be some accidental losses when oil is added to vehicle engines or are "topped up". In the closed system of an automotive transmission, fluids are not frequently changed and the lubricants are effective for the life of the machine. This is not so for engine oils which may be changed about every 5,000 - 10,000 kilometres. As the notified chemical will thermally decompose during use with a concurrent decline in its concentration in the lubricant, there is no expected release of the chemical to the environment under normal conditions of use, except for oil leaks.

5.5. Disposal

A survey by the Australian Institute of Petroleum (AIP, 1995) indicates that of the annual sales of automotive engine oils in Australia, some 60% are potentially recoverable (ie. not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases could be expected to be disposed of responsibly either to oil recycling or incineration. Assuming this is the case, negligible release of the notified chemical should result from these professional activities. The remaining 14% are removed by "do it yourself" (DIY) enthusiasts, and in these cases some of the used oil would be either incinerated, left at transfer stations where it is again likely to be recycled, or deposited into landfill. Meinhardt (2002) estimated that DIY activities account for 7 - 10% of the unaccounted used oil.

According to a survey tracing the fate of used lubricating oil in Australia (Snow, 1997), only around 20% of used oil removed by enthusiasts is collected for recycling, approximately 25% is buried or disposed of in landfill, 5% is disposed of into stormwater drains and the remaining 50% is used in treating fence posts, killing grass and weeds or disposed of in other ways. In a worst case scenario of 14% of the used oil removed by DIY enthusiasts, the notified chemical could be collected for recycling (≤ 28 tonnes), buried or disposed of in landfill (up to 35 tonnes), disposed of in stormwater drains (≤ 7 tonnes) and used in treating fence posts, to kill weeds or disposed of in other ways (≤ 70 tonnes).

Therefore, about 0.7% of the total import volume of the notified substance could be expected to enter the aquatic environment via disposal into the stormwater system. Since the use of the lubricating oils will occur throughout Australia, all releases resulting from use or disposal of used oil will be very diffuse, and release of the notified material in high concentrations is very unlikely except as a result of transport accidents.

Residues in empty containers from garages and DIY consumers would be disposed of in municipal landfills.

5.6. Public exposure

Dermal and ocular exposure to the public may occur during addition and changing of engine oil and collection and disposal of used oil, and while handling car parts coated with oil.

6. PHYSICAL AND CHEMICAL PROPERTIES

The notified chemical is produced in solution in mineral oil. The following physico-chemical properties are for a typical chemical of the same class as the notified chemical and predominantly reflect the properties of the base oil.

Appearance at 20ºC and 101.3 kPa Amber coloured viscous liquid.

Boiling Point 98ºC at 101.3 kPa

Density 1121 kg/m^3

Vapour Pressure Negligible.

Water Solubility Not determined but expected to be low.

Remarks The class of chemicals are formulated for use in oils and have low water solubilities; one member of the class has a solubility of 1.6 mg/L (American Chemistry Council, 2002).

Hydrolysis as a Function of pH Not determined.

Remarks Hydrolysis is unlikely to occur at environmentally relevant conditions based on studies on the class chemicals at 85°C (American Chemistry Council, 2002).

Partition Coefficient (n-octanol/water) log P > 2.49

Remarks The log P for an analogue chemical is 2.49. The notified chemical is expected to have a similar log P.

Adsorption/Desorption Not determined.

Remarks Expected to be relatively high due to its expected low water solubility.

Dissociation Constant Not determined.

Remarks The chemical does not contain any groups that are expected to dissociate.

Particle Size Not applicable.

Flash Point > 95ºC

Flammability Limits Upper: 5%
Lower: 1% (finished lubricant).

Autoignition Temperature > 345ºC (finished lubricant).

Explosive Properties Not considered explosive.

Reactivity Stable.

7. TOXICOLOGICAL INVESTIGATIONS

Toxicological data for the notified chemical were limited to acute oral toxicity in rats, acute dermal toxicity in rabbits and eye irritation in rabbits. A 28-day repeated dose dermal toxicity study was available for a close analogue of the notified chemical and the remaining end points have been obtained with a range of analogues.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 = 2600 mg/kg	low toxicity
Rabbit, acute dermal LD50 > 3160 mg/kg bw	low toxicity
Rabbit, skin irritation (analogues)	corrosive/severely irritating/moderately irritating
Rabbit, eye irritation	severely irritating
Guinea pig, skin sensitisation - adjuvant test/non-adjuvant test (analogues).	limited evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days (analogue MRD-80-53).	NOAEL = 10 mg/kg/day bw No NOAEL established (< 500 mg/kg/day bw)
Rat, dermal repeat dose toxicity – 22 days (analogues)	No NOAEL established
Rabbit, dermal repeat dose toxicity – 21 - 28 days (analogues)	No NOAEL established
Genotoxicity - bacterial reverse mutation (analogues)	non mutagenic
Genotoxicity – in vitro mutagenicity in mouse embryo cells and mouse lymphoma cells (analogues)	genotoxic
Genotoxicity – in vivo mouse micronucleus test (analogues)	non genotoxic
Developmental and reproductive effects (analogue)	NOAEL = 30 mg/kg/day bw for parental animals and pups; no effects on reproductive parameters up to 200 mg/kg/day bw

7.1. Acute toxicity – oral

7.1.1 Notified chemical

TEST SUBSTANCE — Notified chemical.

METHOD
- Species/Strain: Rat/Sprague-Dawley.
- Vehicle: None.
- Remarks - Method: Method similar to OECD TG 401.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 males	681	0/5
2	"	1000	0/5
3	"	1470	0/5
4	"	2150	0/5
5	"	3160	5/5 (days 2 (2), 3(2) and 7)
6	"	4640	5/5 (days 2(4) and 3)
7	"	6810	5/5 (days 2(3) and 3(2))

- LD50: 2600 mg/kg bw
- Signs of Toxicity: Animals dying prior to termination exhibited body weight loss. Excessive salivation, soft stool and faecal staining of the ano-genital area were observed on the day of dosing in most groups. Some animals also exhibited rales and/or motor activity decrease. Additional signs noted subsequently (primarily in animals which died spontaneously) included respiratory decrease, red nasal discharge, general poor condition, urinary staining, ataxia, hypothermia, decreased food consumption, prostration and in single animals tremors and cyanosis.
- Effects in Organs: Animals which died typically exhibited distended stomach, pronounced brain vascularisation, undescended testes, dark red adrenals and

diminished spleen.

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

TEST FACILITY Biodynamics (1980a).

7.1.2 Analogues of the notified chemical (The American Chemistry Council, 2002)

The acute oral LD50 in rats for 8 analogues of the notified chemical ranged from 2000 to 3500 mg/kg bw. Clinical signs included diarrhoea, lethargy, reduced food consumption. Ptosis, piloerection, ataxia and salivation were occasionally observed. Lung congestion, gastrointestinal irritation and a reduction in body fat were observed in some animals.

7.1.3 Analogues of the notified chemical (HSE Toxbase, 1996)

An analogue designated XSA 029J was administered to groups of F344 rats (5/sex) at 2000 mg/kg. One female died. Signs of intoxication following oral administration were salivation, diarrhoea, anogenital staining, hunched posture and unkempt appearance. Additionally in females lethargy, piloerection and encrustation of the periorbital area were observed. There were no treatment related necropsy findings. Plasma cholinesterase was inhibited 56% in males and 64% in females at 24 hours post treatment. Levels returned to normal at 14 days.

An analogue designated DF-11 had acute oral LD50s of 8890 and 7500 mg/kg in rats and mice, respectively.

7.2. Acute toxicity - dermal

7.2.1 Notified chemical

TEST SUBSTANCE Notified chemical.

METHOD Not stated.
Species/Strain Rabbit/New Zealand White.
Vehicle None.
Type of dressing Occlusive.
Remarks - Method Similar to OECD TG 402

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	2/sex	50	None
2	"	200	"
3	"	794	"
4	"	3160	"

LD50 > 3160 mg/kg bw
Signs of Toxicity - Local At doses of 50 and 200 mg/kg bw erythema was slight to severe; at doses of 794 and 3160 mg/kg bw animals exhibited moderate to severe erythema at 24 hours. Oedema ranged from absent to slight. Exfoliation of skin from the dosing site was noted at the highest dose during the second week of dosing, and necrosis of skin at the dosing site was present in 2 of the 4 animals at necropsy.
Effects in Organs Commonly vascularisation of the stomach at all doses; effects on the spleen: diminished, roughened; mottled lungs common at all doses;

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

TEST FACILITY Biodynamics (1980b).

7.2.2 Analogues of the notified chemical

Nine analogues were tested in rabbits and no treatment related mortality was observed at doses from 2000 to 8000 mg/kg bw. Dermal application of the test materials to abraded skin for 24 hours typically produced moderate to severe erythema and oedema, which in some cases persisted through the 14-day observation period. Clinical signs included varying degrees of reduced food consumption, weight loss, diarrhoea, lethargy, ataxia, ptosis, motor incoordination and/or loss of righting reflex.

7.3. Irritation – skin (HSE Toxbase, 1996)

TEST SUBSTANCE	Analogue XSA 029J
METHOD	EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Vehicle	None.
Observation Period	21 days.
Type of Dressing	Semi-occlusive.
Remarks - Method	A brief summary with limited method information was provided.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	2.3	Unknown	21 days	Unknown
Oedema	1.5	"	72 hours	0

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

Remarks - Results	The summary did not include individual scores or animal observations. It states that desquamation was observed at days 7 and 14 but had resolved by day 21.
CONCLUSION	The notified chemical is moderately irritating to skin.

The HSE Toxbase document (HSE Toxbase, 1996) reports that the Chemical Manufacturers Association reviewed data for two groups of analogues. The tests were carried out according to OECD test methods but it is not clear if a 4- or 24-hour exposures were used. The scores for one group indicated moderate irritation to corrosiveness and the other group moderate to severe irritation. It was reported that wiping the residue off with oil reduced the level or irritation. It was also noted that in human repeated patch testing petroleum additives containing 20 – 25% test substance produced marked skin irritation when not wiped off from the application site.

In another report, repeated dermal application of solutions of 2.5 – 50% of analogue DF-11 to rabbits and guinea pigs caused irritation. Dermal application of 1 – 10% solutions in oil gave significant effects, with thickening of the skin, hyperaemia and peeling in guinea pigs. The effects peaked at 20 days and the minimum effective concentration was 2.5%.

7.4. Irritation - eye
7.4.1 Notified chemical

TEST SUBSTANCE	Notified chemical.
METHOD	Not stated.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Observation Period	14 days.
Remarks - Method	Similar to OECD TG 405.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	2.8	3	14 days	2
Conjunctiva: chemosis	3	4	"	3
Conjunctiva: discharge	1.9	3	"	1
Corneal opacity	2.2	4	"	4
Iridial inflammation	1.2	1	7 days	0

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

Remarks - Results	Necrosis of conjunctivae was observed in all animals at the 24, 48 and 72 hour time points and ulceration was observed in one animal at 3 and 4 days and another at 3 days post instillation.
CONCLUSION	The notified chemical is severely irritating to the eye.
TEST FACILITY	Biodynamics (1980c).

7.4.2 Analogues of the notified chemical

XSA 029J was tested in one male New Zealand White rabbit using method EEC B5 and the study was terminated at 48 hours for humane reasons. XSA 029J was a severe eye irritant. Two other classes of analogue were moderate to severe eye irritants. Additive packages containing < 20% analogue are slight to moderate irritants.

7.5. Skin sensitisation (HSE Toxbase, 1996)

Skin sensitisation was determined with analogue XSA 029J in Dunkin Hartley guinea pigs according to the Magnusson and Kligman method using 20 test (10/sex) and 10 control (5/sex) animals. Intradermal induction was with 0.06% test substance and topical induction with 25% test substance in corn oil. The challenge concentration was 10% test substance in corn oil. Three treated animals out of 20 were positive at 24 hours but negative the following day. This study did not suggest the test substance was sensitising to guinea pig skin.

In other studies, repeated application of analogue DF-11 and two other analogues employed in Magnusson Kligman assays were negative. A third analogue was a weak sensitiser in a modified Buehler assay.

The incidence of dermatitis amongst workers using cutting oils containing 8 – 10% of an analogue of the notified chemical was 8 – 12% of 1524 operators as against 13% of 1464 operators using oils not containing the analogue. However, 43% of the first group had folliculitis (inflammation of the hair follicles) as against none in the second group. Workers with positive serological reactions to the analogue numbered 43% in the first group as against 17% in group 2 and 8% in controls. It was concluded there may be some evidence for skin sensitisation potential for analogues of the test substance.

7.6. Repeat dose toxicity

TEST SUBSTANCE	Analogue MRD-80-53.
METHOD	Not stated.
Species/Strain	Rabbit/New Zealand White.
Route of Administration	Dermal – non-occluded.
Exposure Information	Total exposure days: 28 days; Dose regimen: 5 days per week; Post-exposure observation period:
Vehicle	Primol 185.
Remarks - Method	Similar to OECD TG 410.

RESULTS

Group	*Number and Sex of Animals*	*Concentration <%>*	*Mortality*
I (control)	10/sex	0	None
II (low dose)	"	5	None
III (high dose)	"	25	4/20

Mortality and Time to Death
One high dose male died after 30 days on test. Three females died after 17, 23 and 29 days on test.

Clinical Observations
Greater incidence and severity of emaciation and thickening of the outer layer of the skin during the last 2 weeks of the study in high dose animals. A greater incidence of lacrimation was observed in high dose males at week 2 and low and high dose females weeks 2 through 4. Treated animals displayed a higher incidence of mucoidal discharge being more pronounced in high dose animals.

Treated animals exhibited dose-related increases in the incidence and severity of erythema, oedema, atonia, desquamation, fissuring, eschar formation and exfoliation. Many of the observations were moderate to extreme in severity, particularly those in the high dose groups.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Clinical chemistry
Cholesterol was high and albumin lower in high dose animals and cholesterol was also high in low dose females. However, total protein and albumin/globulin ratio were normal. Blood urea nitrogen was elevated in high dose animals and alkaline phosphatase was lower in high dose females. These and other changes were judged to be within normal physiological limits. Cholinesterase was determined in plasma, erythrocytes and brain but clear effects were not evident.

Haematology
Lower haematocrit and red blood cells were observed in high dose animals, the former also in low dose males. Lower haemoglobin was observed in high dose females.

Effects in Organs
Organ weights
Absolute and relative testes and epididymis weights were lower in treated males. Relative adrenal weights were elevated in high dose animals and relative liver weight was elevated in high dose females. Absolute and relative kidney weights were elevated in treated animals except for absolute weights in low dose females.

Histopathology
Gross postmortem examinations confirmed a higher incidence of exfoliation, fissuring, eschar and desquamation in treated animals. Testes were markedly smaller in treated males. The effects on the testes correlated with morphologic abnormalities in the seminiferous tubules that consisted primarily of aspermatogenesis, diffuse tubular hypoplasia and a reduced mitotic activity.

Remarks – Results

CONCLUSION
No No Observed Adverse Effect Level (NOAEL) was established based on marked effects on the testes.

TEST FACILITY Biodynamics (1980d).

In addition to the above study, six other analogues were evaluated in 21 – 28-day repeated dose dermal toxicity studies in rabbits using methodologies consistent with OECD Test Guideline 410 (The American Chemical Council, 2002). The concentration applied to the skin ranged from 3 to 100% and deaths were common at the higher concentrations. Clinical signs included ano-genital staining, nasal and ocular bloody discharge, lacrimation, diarrhoea, lethargy, anorexia, adipsia, loss of body weight, emaciation and behavioural distress. Moderate to severe dermatitis at the site of topical application was observed in all treated animals and to a lesser degree in control animals exposed to the vehicle. Incidence and severity was proportional to concentration and duration of exposure to the test substance. Significant reductions in haemoglobin, haematocrit and erythrocyte

counts were noted in the groups exposed to the test substance. Alkaline phosphatase, blood urea nitrogen, bilirubin, albumin and cholesterol were affected by treatment. Testes and epididymal weights were markedly reduced in the high dose groups. Adrenal and kidney weights were elevated in some higher dose groups. Microscopic examination of the testes revealed aspermatogenesis, diffuse tubular hypoplasia and reduced mitotic activity. No NOAEL was established in any study.

A 28-day repeated oral gavage study in Sprague-Dawley rats with an analogue was commissioned by the Chemical Manufacturer's Association (1995), and reported in HSE Toxbase (1996). Doses were 10, 50, 125, 250 and 500 mg/kg/day. Clinical signs at 125, 250 and 500 mg/kg/day in males and females included discolouration and changes in faecal consistency, staining of body surfaces, rales, salivation and aggression. Rales and salivation were observed in 50 mg/kg/day males. Body weight gain was lower in top dose males through day 12. At necropsy findings in the stomach of 250 and 500 mg/kg/day animals indicated gastric irritation. Mean absolute and relative adrenal weights were increased relative to controls but there were no histopathological correlates. The NOAEL was 10 mg/kg/day based on clinical signs, gastric irritation and increased adrenal weights.

Twenty-one to 28-day dermal toxicity studies were described in detail in HSE Toxbase (1996). Analogue MRD-81-28 was administered to 6 male rabbits at 2 mL/kg of a 25% solution in mineral oil 5 days/week for 29 days. Three treated animals died during the study. Body weight was reduced 31% and skin irritation was evident in treated animals. Testes and epididymes weights were 77 and 74% reduced compared to controls, respectively. Small testes were observed in 4/6 animals and diffuse tubular hypoplasia accompanied aspermatogenesis in all animals with a reduced number of spermatids and/or spermatocytes in some rabbits. A parallel study of the effect of a 30% mean body weight loss relative to the initial mean weight on testicular morphology was undertaken. Animals on the restricted diet showed severe atrophy of the testes with moderately severe tubular hypoplasia and 5/6 rabbits were aspermatogenic.

Further studies were conducted with the same analogue and two other mixed analogues in young and old Sprague-Dawley rats and New Zealand White rabbits. Fifteen male New Zealand White rabbits or Sprague-Dawley rats/group received 2 mL/kg of a 25% solution of the test substances in mineral oil for 5 days/week for 22 days. Clinical signs in both species were alopecia, yellow anogenital staining and emaciation. In rats and rabbits skin irritation was more evident in young than mature animals. Reduced body weights, elevated adrenal weights, reduced testes, epididymes, prostate and seminal vesicle weights were evident in treated animals. At necropsy there was a higher incidence of small testes compared to controls and some discolouration of the liver. Histopathological examination of the testes revealed diffuse hypoplasia and aspermatogenesis in most animals. These changes did not completely reverse during a 4-week recovery period. In rats, adrenal weights of both young and mature animals were higher than controls at the end of the treatment period and low than controls at the end of a 4-week recovery period. Prostate and seminal vesicle weights were reduced over the treatment period and the prostate weight was still reduced at the end of the recovery period. No microscopic changes were noted in the testes of either young or mature rats.

Further investigation of the link between testicular effects in rabbits and skin irritation, weight loss or non-specific stress were undertaken using the analogue MRD-81-28 identified as CMA-102. To investigate the role of skin irritation, animals were treated with 2% sodium hydroxide, 5% hydrochloric acid or irradiated with UVB light. To investigate the role of body weight animals were fasted to produce a body weight decrement of 25%. It was concluded that the testicular changes were not due to stress from skin lesions but were similar to those seen in fasted animals.

7.7 Genotoxicity (The American Chemistry Council, 2002)

Four analogues were negative in bacterial mutagenicity tests conducted in accordance with OECD Test Guidelines 471 and/or 472.

Six analogues were tested in an in vitro point mutation assay in mouse embryo cells. In the absence of metabolic activation 3 studies were positive and 3 negative. In the presence of metabolic activation, 2 studies were positive and 1 negative. This class of chemical substances may therefore exhibit an increased mutagenic potential in the presence of metabolic activation.

Five analogues were tested for mutagenicity in an in vitro mouse lymphoma cell mutagenicity assay (OECD Test Guideline 476). The analogues were negative in the absence of metabolic activation but the weight of evidence is that metabolic activation increases the mutagenic potential of this class of compounds.

Four analogues were negative for clastogenicity in the mouse micronucleus test (OECD Test Guideline 474).

7.8 Toxicity to reproduction – one generation study (The American Chemistry Council, 2002)

TEST SUBSTANCE	Analogue of the notified chemical (CMA 102).
METHOD	OECD Test Guideline 421 Reproduction/Developmental Screening Test.
Species/Strain	Rat
Route of Administration	Oral – gavage.
Vehicle	Corn oil.
Remarks - Method	Males and females received the test substance for 14 days prior to and during the mating period. In addition the females were treated during gestation and through day 4 of lactation.

RESULTS

Group	*Number of Animals*	*Dose mg/kg bw/day*	*Mortality*
1	12/sex	0	0/12
2	"	30	0/12
3	"	100	0/12
4	"	200	2/12 males, 3/12 females

Mortality and Time to Death
Two males and 3 females of the high dose group died.

Effects on Parental (P) animals:
Clinical signs in the decedents included respiratory distress, salivation, hunched posture and mucoid diarrhoea. At necropsy gastric irritation was also observed. Mean body weight gain was reduced in the high dose group. No other macroscopic or microscopic changes were noted and there were no significant treatment related effects on reproductive indices or microscopic anatomy of the reproductive organs in the parents of any group.

Effects on 1st Filial Generation (F1)
Pup viability in the mid and high dose groups was reduced at parturition and in the post-natal period. No treatment related effects were observed on necropsy of the pups found dead or at the scheduled termination.

Remarks - Results	It is noteworthy that the severe effects on the testes seen in rabbit repeated dose studies did not occur in rats and that fertility was normal.

CONCLUSION
The NOAEL was 30 mg/kg/day for the parental animals and the offspring.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

Not determined. However surrogate data exist on two chemical analogues, of relatively low and high molecular weights.

TEST SUBSTANCE	Two analogue chemicals.
METHOD	OECD TG 301 B Ready Biodegradability: CO2 Evolution Test. OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Remarks - Method	No detailed methods were reported aside from a 28-d duration.
RESULTS	Only ≤ 5.9% biodegradation of both analogues indicate poor biodegradability for the chemical class (American Chemistry Council 2002).

8.1.2. Bioaccumulation

Not determined. However, an analogue chemical had a log P of 2.49 indicating a low potential for bioaccumulation. For metal compounds, log P may not be a good indication of bioaccumulation as biological mechanisms for uptake and depuration are complex and variable.

8.2. Ecotoxicological investigations

No data were submitted. Historical aquatic ecotoxicity data on other analogues in the chemical class showed high variability most likely due to non-standardised testing methodologies and problems associated with testing of chemicals with low water solubility. Generally, the toxicity of chemicals to aquatic organisms is correlated with their solubility in water due to bioavailability and uptake factors. Therefore these results were considered unreliable and in September 2002 further testing was proposed. Results of these new tests have not been submitted.

9. RISK ASSESSMENT

9.1.1. Environment – exposure assessment

Possible exposure could result from accidental spillage of bulk containers of the imported additive package containing the notified chemical at < 20%. Losses during blending are low and will be contained before disposal at an approved industrial facility. Incineration of the waste oil will generate water vapour and oxides of carbon. As the only end use of the new chemical is expected to be in engine oil and transmission fluids in an essentially closed system, release to the environment during use should be low. As well, the chemical will thermally decompose during use reducing its concentration in the oil.

The main environmental exposure is expected from inappropriate disposal of new and used engine oils containing < 5% of the notified chemical. Given a worst case scenario of about 14% of oil changes in Australia being performed by DIY enthusiasts, about 7 tonnes of the notified chemical (equivalent to 5% of disposed oils) may be released into stormwater drains and 28 tonnes collected for recycling. Up to 35 and 70 tonnes will be disposed of in landfill and in other ways (treat fence posts, kill weeds etc.), respectively.

The improper disposal to stormwater drains (about 0.7% of the import volume) will be spread across Australia and is expected to partition to organic matter (due to the expected high log P), settle out into the sediments and eventually be degraded. Most of the release due to DIY activities is likely to become associated with soils or sediments, as will chemical released to landfill as container residues. While the chemical's biodegradability is unknown but expected to be slow, it will eventually degrade due to biotic and abiotic processes.

9.1.2. Environment – effects assessment

The toxicity of the notified chemical to aquatic organisms could not be assessed as no data were submitted. The US consortium (American Chemistry Council 2002) summarised old studies on the class of chemicals to which the notified chemical belongs as being unreliable due to inconsistencies in testing methodologies and difficulties in solubilising the material. The resulting EC50 values (exposure durations not specified) ranged from < 0.1 mg/L to > 100 mg/L for single or closely related chemicals. A tentative predicted no effect concentration (PNEC) may be derived by dividing the lowest value by 1000, resulting in a value of 0.1 µg/L.

The acute oral toxicity of a related analogue of the notified chemical to rats showed low toxicity with an LD50 > 2000 mg/kg bw. Similarly, a low acute dermal toxicity to rabbits was shown with an LD50 > 2000 mg/kg bw.

9.1.3. Environment – risk characterisation

A worst case predicted environmental concentration (PEC) from the release of the notified chemical into stormwater drains can be calculated by assuming that all of the 5% of the disposed oil from DIY operations (7 tonnes) were used in a single metropolitan area with a geographical footprint of 500 km^2 and an average annual rainfall of 500 mm. With a maximum annual release into this localised stormwater system of 7000 kg and the annual volume of water drained from this region estimated to be approximately 2.5×10^{11} L, the resultant PEC is approximately 0.028 µg/L averaged out in a year. Given that releases of the chemical will be very much more diffuse than estimated here, the PEC should be lower still.

Although no comparison can be made between the PEC and a PNEC for the notified chemical (due to the lack of ecotoxicity data), the risk is expected to be acceptable due to the low PEC and the chemical's expected strong partitioning to soils and sediments. The bioavailability to aquatic and terrestrial organisms will be reduced due to this binding. A crude calculation using the tentative PNEC above confirms this.

However, in the case of a sizeable release to waterways, the potential exists for physical fouling of aquatic organisms by undissolved material. Therefore, large volumes of the notified chemical should be prevented from entering waterways.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical is to be imported in an additive package at less than 20% and diluted to less than 2% for use in oils. Typically exposure during blending is controlled by the use of personal protective equipment and exposure to aerosols is minimised by the use of local exhaust ventilation at points of release. Dermal exposure should be intermittent and limited to connection and disconnection of transfer equipment and cleaning of lines. Therefore, exposure is typically low. Nevertheless when exposure to a viscous liquid containing the notified chemical does occur it can potentially last several hours unless the substance is removed from the skin.

During use of the oil containing the notified chemical by mechanics dermal and possibly eye contact can occur during changing engine oil and more intermittently to transmission fluids. Exposure to the oil can be quite extensive in these circumstances but exposure to the notified chemical is limited by its low concentration (< 2%) in the oil.

9.2.2. Public health – exposure assessment

Exposure of the public can occur during oil changes but the exposure is limited by the fact it is intermittent and the concentration of the notified chemical in the oil is low.

9.2.3. Human health - effects assessment

A range of studies was conducted on the notified chemical but there was also considerable information on analogues. These analogues differed only in the identity of substituent alkyl groups and the main toxicological features were present in all cases.

Acute oral and dermal toxicities of the notified chemical are expected to be low (LD50 > 2000 mg/kg bw. Skin irritation in rabbits (for close analogues) was moderate to severe with some suggestion of corrosivity although the study suggesting skin corrosivity lacks experimental detail. In the repeated dose dermal toxicity studies, application of up to 25% test substance for up to 28 days was at most severely irritating. The notified chemical was a severe eye irritant in rabbits. Analogues were not mutagenic in bacteria and not clastogenic in the mouse micronucleus test but may be weakly mutagenic in mouse cells in vitro. Skin sensitisation studies and human epidemiological evidence suggest analogues of the notified chemical may be weakly skin sensitising although the irritant nature of the analogues could preclude using concentrations high enough for induction.

Repeat dose studies (both oral and dermal) suggested severe effects on the male reproductive organs of rabbits but these effects were shown to be secondary to severely reduced body weight. In a variety of studies the adrenals were elevated in weight in rats and rabbits but no histopathological correlates suggested limited organ toxicity. Some cholinesterase inhibition was observed but this was judged not to be a severe effect.

An analogue of the notified chemical had no reproductive or developmental effects in rats.

9.2.4. Occupational health and safety – risk characterisation

There may be a risk of serious eye damage and skin irritation (based on results of dermal repeat dose studies using similar formulations) to oil blending workers from the imported additive packages. However, exposure is likely to be to small amounts and to occur intermittently only in the case where impervious gloves and goggles are not worn. Therefore the risk of skin or eye irritancy is low. There would be a low risk of skin sensitisation particularly as contact should be intermittent.

There should be a low risk of skin or eye irritancy or skin sensitisation to mechanics handling oil containing the notified chemical at < 2% or automotive parts which have been in contact with the oil.

9.2.5. Public health – risk characterisation

There should be a low risk of skin or eye irritancy or skin sensitisation to the public on exposure through changing engine oil or transmission fluids containing the notified chemical, or handling automotive parts which have been in contact with the oils given the intermittent and low exposure and the low concentration of the notified chemical in the oil.

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

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R38 Irritating to skin
R41 Risk of serious damage to eyes

and

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.

Acute toxicity (category 5), skin irritant (category 2) and eye irritant (category 1)

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 Moderate Concern to occupational health and safety under the conditions of the occupational settings described based on the risk of skin and eye irritancy to oil blending workers.

10.3.2. Public health

There is Negligible Concern to public health when used as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing the 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 containing the 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

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:

R38: Irritating to skin;
R41: Risk of serious damage to eyes

- Use the following risk phrases for products/mixtures containing the notified polymer:
  - ≥ 20%: R38
  - ≥ 10%: R41
  - 10% ≥ conc ≥ 5%: R36

CONTROL MEASURES
Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Impermeable gloves, protective clothing, chemical goggles, industrial footwear.

  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

Disposal

- The notified chemical should be disposed of by placing contaminated material in containers and disposed of according to the applicable regulations.

- The notified chemical should not be disposed of in waterways and stormwater drains.

Storage

- The following precautions should be taken regarding storage of the notified chemical:
  - Store between 10 and 40°C at atmospheric pressure.
  - Keep container closed and handle with care. Open slowly in order to control possible pressure release. Store in a cool, well-ventilated place away from incompatible materials.
  - Extreme caution must be used in tank gauging or similar operations because overheating could cause lethal concentrations of hydrogen sulfide to accumulate in the head space of containers.
  - Do not handle, store or open near an open flame, sources of heat or ignition. Protect material from sunlight.
  - This material is not a static accumulator but use proper bonding and/or grounding procedures.
  - Do not pressurise, cut, heat or weld containers. Empty product containers may contain residues. Do not reuse empty containers without commercial cleaning or reconditioning.

Emergency procedures

- Spills/release of the notified chemical on land should be contained with sand or earth. Recover by pumping or scrape up with shovels and place in suitable containers for recycling or disposal by local regulations.

- For spills in water, other shipping should be warned and the port or relevant authority

should be notified. Shut off source and confine if possible. Remove from surface by skimming or with suitable absorbents. If allowed by local authorities and environmental agencies, sinking and/or suitable dispersants may be used in nonconfined waters. Consult an expert on disposal of any recovered material and ensure conformity to local disposal regulations.

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(1) of the Act; if

- When the High Production Volume (HPV) consortium releases its report on additional environmental fate and toxicity testing on this class of chemical, a reassessment of the environmental risk may be necessary and the report should be forwarded to the Director for consideration.

or

(2) 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.

13. BIBLIOGRAPHY

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*The identity of the chemical class is in the exempt information section of the Assessment Report.