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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Component of Additiv 104

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Castrol Australia Pty Ltd (ABN 20 003 663 474), 132 McCreadie Rd GUILDFORD NSW 2161.

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 identity

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: hydrolysis as a function of pH, dissociation constant, particle size, flammability limits, bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
USA: PMN-98-1154; Canada: NSN #11679.

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Additiv 104, Additive FR and Intermediate 93853 refer to the same formulation. Greases formulated with Additiv 104 containing less than 2% of the notified chemical are to be imported and are designated PD-00, PD-0 and PD-2. Gear oils containing less than 2% notified chemical also will be imported as will a gear oil concentrate containing 13% notified chemical.

CAS NUMBER
Not assigned.

MOLECULAR WEIGHT
Average molecular weight is 1020.

SPECTRAL DATA

METHOD	Infrared spectrum of a liquid film between two ZnSe disks.
Remarks	Characteristic spectrum produced.
TEST FACILITY	RCC (1993a).

METHOD	Ultraviolet/visible light spectrum of a chloroform solution.
Remarks	No spectra for acidic or alkaline conditions were performed. One absorbance maximum at 322 nm was observed.
TEST FACILITY	RCC Notox (1993a).

METHOD	^{1}H nuclear magnetic resonance spectrum.
Remarks	Characteristic spectrum was produced.
TEST FACILITY	RCC (1993b).

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Infrared, ultraviolet/visible and nuclear magnetic resonance spectroscopy (RCC, 1993a, b; RCC Notox, 1993a).

3. COMPOSITION

DEGREE OF PURITY
> 99.7%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None.

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

ADDITIVES/ADJUVANTS
None.

Additiv 104 contains 70 – 75% notified chemical and 25 – 30% hydrotreated heavy naphthenic petroleum distillate.

4. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1	1.2	1.4	1.6	1.6

USE
Additive used mainly in greases but also in gear oils. The finished greases and oils are designed for use in industrial machinery in a large number of industries including printing, mining, textile, food and beverage, transport, chemicals/plastics, and manufacturing.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not stated.

IDENTITY OF MANUFACTURER/RECIPIENTS
Wide range of industrial machinery using a variety of grease and oil types.

TRANSPORTATION AND PACKAGING
The gear oils and greases containing < 2% notified chemical may be imported in 18 kg plastic pails, 180 kg steel drums, 50 kg, 20 kg, 15 kg, 5 kg and 1 kg plastic pails and 280 g and 450 g cartridges.

A gear oil concentrate containing 13% notified chemical will be imported in 180 kg drums.

5.2. Operation Description

Gear oils will be added to gearboxes by pump or using a funnel. Greases can be applied by hand or by air powered grease gun. Grease guns would normally be filled by hand.

The gear oil concentrate is blended and dispensed with automated equipment.

Repacking of greases from 180 kg drums to smaller containers is accomplished by a air operated

grease pump.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Blender/Packager/Repackager	3	Up to 8 hours/day	Up to 50 days per year
Fitters	> 1000	Up to 8 hours/day	Up to 230 days/year

Exposure Details

Potential exposure during repackaging of greases or blending/packaging of gear oils will mainly occur during connection of transfer systems and cleaning and maintenance of equipment. Oil impervious and solvent resistant gloves (PVC or nitrile), oil impervious clothing and non-slip footwear are worn where prolonged contact with skin is unavoidable.

Some spillage of gear oils and semi-fluid greases containing the notified chemical may be expected during addition to and removal from gearboxes. Dermal exposure is possible during clean up operations. Dermal exposure to grease is possible during application or filling of grease guns although dispersion of greases is unlikely due to their semi-solid state. The notified chemical is present in the greases or gear oils at less than 2% and this determines the maximum worker exposure in these products. However, the maximum worker exposure to the notified chemical is to the gear oil concentrate at 13%.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as an additive in a range of lubricant products, to be sold as gear oils and greases of varying viscosity grades. The products containing the notified chemical will be imported in 180 kg steel drums and then either blended with other components (i.e. base oils to produce gear oils of viscosities 46 to 680 cst), or will be directly repacked into smaller containers. The final container sizes will vary depending on the end use and target industry, and will range from 5-20 kg plastic pails, and 450 g to 15 kg cartridges and grease guns. The notified chemical will be present in the finished lubricants at up to 2%.

No release of the notified chemical contained in the lubricants is anticipated during blending or repackaging, except in the event of an accidental spill. The MSDS contains suitable procedures for containing spills. The 180 kg import drums and any remaining residues are collected by drum reconditioners for recycling.

RELEASE OF CHEMICAL FROM USE

Release of the lubricants may occur at end use in the event of a spill during initial lubrication, through disposal of used oils and as residues in used containers. The greases containing the notified chemical are generally applied by sealed cartridges and grease guns and are in the form of a semi-solid gel or paste, hence release due to spills will be limited and easily contained for disposal. The MSDS contains suitable procedures for containing any spills. Spent cartridges containing residues are placed in industrial bins. Greases are normally disposed of by incineration.

The gear oils are available in 12 viscosity grades. The specialised lubricant oils are normally applied via a pumping system to sealed gear boxes or circulating systems, and hence no release is anticipated during use. However, release of oils could occur in the event of spills during top up and during removal and disposal of used oils. The notifier indicated that old oils are normally drained from the gear boxes/circulating systems and the used oil is placed in waste oil drums for collection by a licensed oil refinery company or waste oil collector for disposal or recycling. Small spills cleaned up with a suitable absorbent and containing no free oil are deemed suitable for disposal in landfill. Containers and their residues are disposed of in industrial bins in accordance with State EPA regulations.

5.5. Disposal

The waste is expected to be disposed of in accordance with State EPA regulations. The normal means of disposal of used oils and greases is by incineration and recycling. Small spills without free oil are deemed suitable for incineration or disposal in landfill.

5.6. Public exposure

The imported products containing the notified chemical will not be sold to the public and public exposure is not expected except if a major accident occurs during transport to customers. Disposal of spent oils or greases should be conducted by licensed contractors and public exposure is unlikely.

6. PHYSICAL AND CHEMICAL PROPERTIES

The studies outlined below were conducted on Additiv 104.

Appearance at 20ºC and 101.3 kPa Viscous dark red solution (at a concentration of > 50% in mineral oil).

Boiling Point Decomposes at temperatures above 150ºC at 101.3 kPa

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks When heated above 150ºC in a Differential Scanning Calorimeter an exothermic effect which increased with increasing temperature was observed.
TEST FACILITY RCC Notox (1993c).

Density 1068 kg/m^3 at 20ºC

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
TEST FACILITY RCC Notox (1993d).

Vapour Pressure 0.72 ± 0.04 Pa at 25ºC (or 20ºC).

METHOD Based on OECD TG 104 Vapour Pressure, and EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks In total 111 pressure measurements were performed at 3 different temperatures. Measurements were started at 35ºC using the 133000 Pa sensor. After measurement 25, vapour pressure data were collected using the 133 Pa sensor. Data collected after measurement 55, when decreases in vapour pressure and loss of test substance were negligible, were used to calculate the final result. The results indicate the notified chemical is moderately volatile (Mensink *et al*. 1995).
TEST FACILITY RCC Notox (1993e)

Water Solubility < 8.5 X 10^{-4} g/L at 20ºC

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks In a preliminary test, 42 mg test substance was stirred over night in 25 mL distilled water and the concentration dissolved in solution was determined by spectrophotometric methods. The test substance formed a turbid white solution, and no phase separation was achieved by centrifuging and filtration. The concentration of the test item in solution could not be quantified as it was below the limit of detection of the method. Visual observation indicated the presence of solid test substance after stirring for 26 hours. The notified chemical is slightly soluble in water (Mensink *et al*. 1995).
TEST FACILITY RCC Notox (1993f)

Hydrolysis as a Function of pH Not determined

Remarks The notified chemical could be expected to hydrolyse under suitable conditions. However, the low water solubility of the greases in which the notified chemical is an additive would preclude hydrolysis as an important transformation mechanism.

Partition Coefficient (n-octanol/water) log Pow at 20°C > 6.1

METHOD OECD TG 117 Partition Coefficient (n-octanol/water), HPLC Method.
Remarks The solubility of the notified chemical in n-octanol was determined by adding increasing amounts (36 mg, 2.48 g, 6.74 g, 6.17 g, 10.82 g) of the test substance up to 26.6 g to n-octanol and stirring after each addition for 10 minutes, 2 hours, and 1 hour, respectively. The concentration in solution was determined using a spectrophotometric method to be >1000 g/L. The partition coefficient was estimated at the quotient of the n-octanol and water solubility. The test substance is highly lipophilic.
TEST FACILITY RCC Notox (1993g)

Adsorption/Desorption log K_{oc} = 5.6 (95% CI = 5.23-6.03).

Remarks The soil partition coefficient was estimated according to the method of Seth *et al* (1999), using the following relationships: Koc = 0.35 Pow, with a lower limit determined by Koc = 0.14 Pow and an upper limit determined by Koc = 0.89 Pow. The results indicate the notified chemical is strongly adsorbed to soil and is not likely to leach into surface or groundwater.

Dissociation Constant Not determined

Remarks The notified chemical does not dissolve in water and hence is not able to dissociate.

Particle Size Liquid.

Flash Point > 200°C at 101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.
TEST FACILITY RCC Notox (1993h).

Flammability Limits Not determined.

Autoignition Temperature 395°C.

METHOD 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
TEST FACILITY RCC Notox (1993i).

Explosive Properties Not explosive when exposed to thermal or mechanical stress.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
TEST FACILITY RCC Notox (1993j).

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	moderately irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test.	evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOEL = 200 mg/kg/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberrations	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE Additiv 104.

METHOD OECD TG 401 Acute Oral Toxicity.
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).
Species/Strain Rat/Wistar.
Vehicle polyethylene glycol

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	None.

LD50 > 2000 mg/kg bw
Signs of Toxicity Alopecia in 3 females; 5 animals showed lower than expected body weight gain over the second week of the study.
Effects in Organs None.

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

TEST FACILITY RCC Notox (1993k).

7.2. Acute toxicity - dermal

TEST SUBSTANCE Additiv 104.

METHOD OECD TG 402 Acute Dermal Toxicity.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain Rat/Wistar.
Vehicle polyethylene glycol
Type of dressing Occlusive.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	1000	None.
2	5/sex	2000	None.

LD50 > 2000 mg/kg bw
Signs of Toxicity - Local Erythema between days 2 and 15, scales, days 4 – 15 and scabs, days 5 – 15.
Signs of Toxicity - Systemic None.
Effects in Organs Scab formation on the treated skin of one male and one female exposed at

1000 mg/kg bw and of 3 females at 2000 mg/kg bw.

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

TEST FACILITY RCC Notox (1993m).

7.3. Acute toxicity - inhalation

No data provided.

7.4. Irritation – skin

TEST SUBSTANCE Additiv 104.

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None.
Observation Period	21 days.
Type of Dressing	Semi-occlusive.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	2	1.67	1.67	4	21 days	1
Oedema	2.33	3	3	3	21 days	1

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

CONCLUSION The notified chemical is moderately irritating to skin.

TEST FACILITY RCC Notox (1993n).

7.5. Irritation - eye

TEST SUBSTANCE Additiv 104.

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	7 days.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1.67	2.67	2	3	72 hours	0
Conjunctiva: chemosis	1	1	1.33	2	72 hours	0
Conjunctiva: discharge	0.33	1	1	1	72 hours	0
Corneal opacity	0	0	0	0		0
Iridial inflammation	0	0	0	0		0

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

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY RCC Notox (1993o).

7.6. Skin sensitisation

TEST SUBSTANCE Additiv 104.

METHOD OECD TG 406 Skin Sensitisation – maximisation test.
EC Directive 96/54/EC B.6 Skin Sensitization – maximisation test.

Species/Strain Guinea pig/Himalayan.

PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: < 5% (w/w)
topical: 10% (w/w)

MAIN STUDY

Number of Animals Test Group: 20 Control Group: 10

INDUCTION PHASE Induction Concentration:
intradermal injection : 1% (w/w)
topical application: 15% (w/w)

Signs of Irritation Eighteen animals showed slight or well-defined erythema after the 48 hours occluded epidermal induction exposure.

CHALLENGE PHASE

1st challenge topical application: 10%, 5% and 2% (w/w)

2nd challenge topical application: 0.1%, 0.05% and 0.02% (w/w)

RESULTS

Animal	*Challenge Concentration (% w/w)*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	10	20/20	20/20		
	5	19/20	20/20		
	2	18/20	20/20		
	0.1			10/20	8/20[b]
	0.05			10/20	6/20[b]
	0.02			7/20[a]	3/20[b]
Control Group	10	10/10	10/10		
	5	10/10	10/10		
	2	10/10	10/10		
	0.1			2/10	1/10[c]
	0.05			2/10	0/10[c]
	0.02			2/10	0/10[c]

[a] 2 animals exhibited scaliness; [b] 13, 11 and 3 animals exhibited scaliness at concentrations of 0.1, 0.05 and 0.02%, respectively; [c] 4, 2 and 2 animals exhibited scaliness at concentrations of 0.1, 0.05 and 0.02%, respectively

Remarks - Results Positive readings were slight (Draize score of 1) for all animals exhibiting erythema in the 2nd challenge.

CONCLUSION There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY RCC Notox (1993p).

7.7. Repeat dose toxicity

TEST SUBSTANCE Additiv 104.

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain

Route of Administration Oral – gavage.

Exposure Information Total exposure days: 28 days;
Dose regimen: 7 days per week;
Post-exposure observation period: 14 days

Vehicle propylene glycol

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	1 female on day 28
II (low dose)	5/sex	50	None
III (mid dose)	5/sex	200	None
IV (high dose)	5/sex	1000	None
V (control recovery)	5/sex	0	None
VI (high dose recovery)	5/sex	1000	None

Mortality and Time to Death

One control female died on the day of study termination of undetermined cause.

Clinical Observations

Salivation and rales were observed in the high dose group. Hunched posture in 10/10 females and rough coat in 4/10 females of the high dose group. Body weights and body weight gain of high dose males were lower than control during weeks 2 to 4 and during the recovery period but there were no differences in food consumption. No ophthalmoscopic findings at weeks 4 and 6 in any group.

Laboratory Findings – Clinical Chemistry, Haematology

Clinical chemistry: High dose animals exhibited some statistically significant changes; males, lower total bilirubin, glucose and alkaline phosphatase and higher alanine aminotransferase (ALAT); females, lower total bilirubin and aspartate aminotransferase and higher potassium. Except for ALAT, the changes were within the normal range of variation or were explicable on the basis of abnormal control values.

Haematology: Lower haemoglobin and haematocrit occurred in low and high dose males but not mid dose males which suggested these were not treatment-related effects; lower mean corpuscular volume and elevated red cell distribution width in high dose males were small effects and not seen in females; no effects occurred in high dose females.

Effects in Organs

No differences in absolute or relative organ weights occurred in high dose animals at week 4. A few changes noted in recovery animals (elevated brain/body weight and lower absolute liver weight in males; elevated absolute brain weight in females) were within normal background variation.

All animals of the high dose groups at 4 weeks exhibited hyperplasia and keratinisation of the forestomach. In some animals severe to very severe hyperplasia was associated with moderate to severe submucosal oedema, necrotic areas and infiltrates of inflammatory cells.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 200 mg/kg bw/day in this study, based on clinical signs, lower body weights in males and local irritant effects on the forestomach in all animals at the higher dose level.

TEST FACILITY RCC Notox (1993q).

7.8. Genotoxicity - bacteria

TEST SUBSTANCE	Additiv 104.
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure and Pre incubation procedure.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2 *uvr*A, WP2.
Metabolic Activation System	Aroclor 1254-induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 10 - 5000 µg/plate. b) Without metabolic activation: 10 - 5000 µg/plate.
Vehicle	A 1 + 9 dilution of dichloromethane with dimethylsulfoxide.
Remarks - Method	The repeat experiment included a pre incubation procedure.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	2500	1000	-	-
Test 2		2500	-	-
Present				
Test 1	5000	1000	-	-
Test 2		2500	-	-

Remarks - Results	Cytotoxicity was measured as a reduction in number of revertants per plate and appeared to be slightly greater for the *E. coli* strains.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	CCR (1993a).

7.9. Genotoxicity – in vitro

TEST SUBSTANCE	Additiv 104.
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line	Chinese Hamster V79 cells.
Metabolic Activation System	Aroclor 1254-induced rat liver S9 fraction.
Vehicle	A 1 + 9 dilution of dichloromethane with dimethylsulfoxide.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	1, 3, 10	4 hours	18 hours
	10	"	28 hours
Test 2	1, 3, 10	"	18 hours
	15		28 hours
Present			
Test 1	3, 10, 30	"	18 hours
	30	"	28 hours
Test 2	3, 10, 20	"	18 hours
	6		28 hours

Above cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	25	10 (only at 28 hours)	-	-
Test 2		15	-	-
Present				
Test 1	50	30	-	-
Test 2		-	-	-

Remarks - Results: Cytotoxicity in the main test was indicated by a reduction in mitotic index but was a reduction in colony forming ability in the preliminary test.

CONCLUSION: The notified chemical was not clastogenic to Chinese Hamster V79 cells treated in vitro under the conditions of the test.

TEST FACILITY: CCR (1993b).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: ADDITIV 104

METHOD: EEC directive 92/69, Part C: Methods for the determination of ecotoxicity, Publication No. L383, December 1992, C.4. Biodegradation: determination of the ready biodegradability, C.4.C: Carbon dioxide (CO_2) evolution test (Modified Sturm Test).

Inoculum	Municipal sewage sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	CO_2 production, Dissolved organic carbon (DOC).
Remarks - Method	Duplicate samples of test substance in amounts corresponding to 15 mg/L TOC were incubated with sewage sludge, along with an inoculum blank, a procedure control containing the reference substance, sodium acetate plus inoculum, and a toxicity control containing the test substance, sodium acetate and inoculum. Measurements of CO_2 production were made every second or third day up to 10 days, and then every fourth or fifth day until the end of the test. DOC was measured on day 28.

RESULTS

Test substance		*Sodium acetate*	
Day	*% degradation*	*Day*	*% degradation*
10	<3	10	53
28	<8	28	88

Remarks - Results: The test substance was toxic to microorganisms in the test, as only 20% of sodium acetate was degraded by day 28 in the toxicity control compared to the 88% degradation in the reference sample. Less than 8% of the notified chemical was degraded in the test suspension containing only inoculum.

CONCLUSION: The test substance is not readily biodegradable under the conditions of the test.

TEST FACILITY: RCC Notox (1993r)

8.1.2. Inherent biodegradability

TEST SUBSTANCE: ADDITIV 104

METHOD: OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).

Inoculum	Activated sewage sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biochemical oxygen demand (BOD), HPLC
Remarks - Method	Duplicate samples containing either 30 mg test substance in purified water, or 30 mg test substance and 9 mg activated sludge, were incubated for 28 days in 300 mL of basal culture medium. In addition, 1 blank control containing 9 mg activated sludge was incubated in 300 mL of basal culture medium. The concentration of the test substance and the degradate, Di-ethoxylated Fat Amine, remaining in solution at the termination of the test was determined by HPLC. Oxygen consumption was determined for day 7, 14, 21 and 25.

RESULTS	In the two replicate vessels containing the test substance and sludge, 95% and 54% was degraded by the end of the test. In the test solution without sludge, more than 50% of the test substance was degraded, indicating abiotic degradation had occurred. It was anticipated that the test substance would hydrolyse to di-ethoxylated fat amine and molybdenum; however, no di-ethoxylated fat amine was found in the test solution. In addition, no peaks identifying other hydrolysis products were found. Measurement of the BOD indicated that only 13% was biodegraded after 25 days. Therefore, it could not be determined from the test results whether the test substance incubated with sludge was degraded by biotic or abiotic mechanisms.
Remarks - Results	The study authors concluded that most of the test material was hydrolysed during the test, with about 13% of the test substance biodegraded by the end of the test. The hydrolysis products could not be identified.
CONCLUSION	The test substance is poorly biodegradable under the conditions of the test.
TEST FACILITY	Kurume Research Laboratories (1996).

8.1.3. Bioaccumulation

No data were provided. The notified chemical has a high affinity to lipids, which suggests a potential to bioaccumulate. However, the low water solubility and high molecular weight should prevent the substance crossing biological membranes.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	ADDITIV 104
METHOD	EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – Static conditions.
Species	*Cyprinus carpio*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	pH, dissolved oxygen, temperature.
Remarks – Method	Following a range finding test, 7 fish per concentration were exposed for 96 hours to the water available fraction (WAF) of the test substance. The amount of dissolved test item in the WAF could not be determined analytically due to the low sensitivity of the method. The final test solutions ranged in appearance from clear to turbid. In the test vessel with the highest concentration, particles of the test substance were deposited on the bottom of the vessel. The amount of test substance in the WAF was estimated to be 20%. These estimates were performed by spreading weighed amounts of test material on an inert surface (i.e. microscope slides) then allowing the material to reach equilibrium in the water. The amount of material remaining on the slide was then determined by weighing after removal of the WAF.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*	
Nominal		*24h*	*96h*
0	7	0	0
10	7	0	0
18	7	0	0

32	7	0	0
56	7	0	0
100	7	7	7

LC50	10-20 mg/L at 96 hours, based on the estimation of 20% dissolved in the WAF or 56-100 mg/L based on nominal concentrations.
Remarks – Results	No fish died at nominal concentrations below 100 mg/L.

CONCLUSION The test substance is slightly toxic to fish (Mensink *et al*. 1995).

TEST FACILITY RCC Notox (1993s)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE ADDITIV 104

METHOD EC Directive 92/69/EEC C.2 Acute Toxicity/immobility for Daphnia – Static conditions.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	pH, Oxygen concentrations, temperature
Remarks - Method	Following a range finding test, 2 replicates of 10 Daphnia per concentration were exposed to the water available fraction (WAF) of the test chemical or a control for 48 hours. A reference test using potassium dichromate was also performed to check the sensitivity of the test system. The concentrations in the WAF were not determined. The EC50 was calculated from the probits of the percentages of affected Daphnia and the logarithms of the WAF using the maximum likelihood estimation.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		20	0	0
10	Not measured	20	0	0
18	"	20	0	1
32	"	20	3	4
56	"	20	13	20
100	"	20	20	20

EC50	34 mg/L at 48 hours (nominal) (CI= 25-65 mg/L)
LOEC	18 mg/L at 48 hours
Remarks - Results	The responses to the reference test were within the ranges of the expected responses at the different concentrations. The 48 h EC50 for the reference substance was 0.46 mg/L.

CONCLUSION The test chemical is slightly toxic to *Daphnia magna*.

TEST FACILITY RCC Notox (1993t)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE ADDITIV 104

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	12.5, 25, 50, 100 and 200 mg/L

Nominal Concentration Range Measured	<LOQ for all concentrations (LOQ = 0.112 mg/L).
Auxiliary Solvent	None
Analytical Monitoring	Test concentrations were determined by HPLC at 0-72 hours.
Remarks - Method	Following a range finding test, algae (10^4 cells per mL) were exposed to the water available fraction (WAF) of the test chemical over the concentration ranges above. Prior to exposure, the test material was stirred for 23 hours and the WAF was removed by filtration when globules of micro-dispersion appeared in the aqueous phase. Samples were removed at 0, 24, 48 and 72 hours and the cell densities were determined with a particle counter. Results were analysed by statistical methods. The pH deviation in the control cultures was less than 1.5 pH units after 72 hours and therefore was within the limits given in the Test Guidelines.

RESULTS

EbL50	26 mg/L loading rate WAF at 72 hours (95% CI, 22-31 mg/L)
ErL50	56 mg/L loading rate WAF at 72 hours (95% CI, 50-62 mg/L)
NOEC	12.5 mg/L loading rate WAF at 72 hours
Remarks - Results	All loading rates above 12.5 mg/L resulted in significant differences between the test groups and the control groups. No abnormalities were observed in the test or control cultures. However, as no chemical was detected above LOQ (0.112 mg/L) in the test medium by HPLC, but an unidentified peak was detected in the WAF, the toxicity results could not be attributed to a single component or a mixture of components in the whole test material.

CONCLUSION	The WAF of the whole test material is slightly toxic to algae (Mensink *et al*. 1995).
TEST FACILITY	Safepharm Laboratories (2002)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is an additive in specialised lubricant products of varying viscosity grades, which are intended for use in industrial machinery. No environmental release of the lubricants is anticipated during transport and repackaging, except in the event of an accidental spill. Some release of the chemical in lubricants could occur at end use during disposal of used oils and residues in used containers.

No estimates of the amounts of waste were provided. We expect the amount of waste from spills to be negligible, particularly for greases. The greases containing the notified chemical are packaged in sealed containers in the form of semi-solid gels or pastes, hence spills are minimised and easily contained. The lubricant oils are normally applied via a pumping system to enclosed and often permanently sealed gear systems, and this is also expected to minimise spills.

It is anticipated that spills and residues will be incinerated or landfilled. If we assume 2% of the notified chemical remains in containers, or is spilled, a maximum of 32 kg of notified chemical could be disposed of in a diffuse manner in landfill or by incineration. Incineration would result in the production of oxides of carbon, nitrogen and molybdenum. The estimated log Koc and low water solubility indicates that the notified chemical will be immobile in soil environments. While not readily biodegraded by sewage micro-organisms, the chemical is likely to be slowly degraded in soil environments by soil microbes and abiotic processes.

The notifier recommends that clients dispose of used lubricating oils through a licensed oil refinery company or waste oil collector for recovery or recycling. However, based on available information of the fate of used lubricating oils (AIP 1995; 1998), about 60% of all used oils generated in Australia are collected for recycling to be resold mainly as fuel oil. The fate of the remaining 40% of used oil not collected for recycling is uncertain. Snow (1997) traced the fate of used lubricant oils (used in motor vehicles) removed by DIY enthusiasts, and found that about 20% is collected for recycling, 25% is sent to landfill, 5% is disposed of into stormwater drains, and the remaining 40% is reused to treat wooden fence posts, kill grass and weeds, or to suppress dust. While the lubricating oils will not be used in motor vehicles by DIY users, the studies suggest a potential for direct environmental release if used oils are disposed of inappropriately either by ground dumping or dumping into the sewer.

The amount entering the environment via irresponsible disposal is difficult to predict, especially for industrial applications. We expect that most industrial customers will dispose of oils through appropriate channels. Nevertheless, we have calculated a worst-case daily PEC in sewage effluent of 0.014 µg/L assuming 5% of customers dispose of used oil inappropriately into the sewer. The PEC also assumes 50% of the annual import volume is used in gear oil applications, of which half requires disposal, resulting in a maximum of 20 kg annually of notified chemical being dumped inappropriately. We assume the PEC is diluted by a factor of 10 to 0.0014 µg/L in the ocean and with no dilution in rivers.

9.1.2. Environment – effects assessment

The notified chemical is slightly toxic to fish, Daphnia and algae in acute toxicity tests. The most sensitive organism is algae with a 72 h EC50 (biomass) of 26 mg/L (nominal) and NOEC of 12.5 mg/L (nominal). The resulting PNEC, using a safety factor of 1000, is 26 µg/L.

9.1.3. Environment – risk characterisation

Release of the notified chemical into the aquatic environment during normal use does not occur; however, there is a potential for direct environmental release if used oils are disposed of inappropriately either by ground dumping or dumping into the sewer. We have calculated a worst-case daily PEC in sewage effluent of 0.014 µg/L, assuming 5% of customers dispose of used oil inappropriately into the sewer. The PEC also assumes no adsorption or degradation in the sewer. The resulting PEC/PNEC ratio is 5.4×10^{-4}, which is orders of magnitude less than one, indicating a low concern for aquatic organisms.

Owing to the chemical's low water solubility, and strong affinity to lipids, most of the chemical finding its way into the sewer would ultimately end up in the soil rather than in the aquatic environment due to adsorption to particulate matter and later settling to sludge. Its low mobility in soil indicates the notified chemical is unlikely to represent a risk for contamination of ground or surface water. Nevertheless, the toxicity tests indicate the presence of water soluble toxic component in the WAF, occurring at low concentrations, which could represent a hazard if significant amounts of the used oils were released into the environment. However, release through improper disposal is expected to be minimal for lubricants sold to the industrial market, where most used oils are likely to be disposed of by recycling, burning or refining. Disposal considerations on the MSDS are currently indicated by a disposal code of European origin. We recommend that these be changed to reflect disposal regulation in Australia and to emphasise appropriate methods of disposal.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be imported as a component of greases and, to a lesser extent, gear oils at less than 2%. A gear oil concentrate containing 13% notified chemical will also be imported for blending into gear oil products. Transport and storage workers should not be exposed to the greases or oils except in the event of an accident which leads to rupture of containers.

Blending of gear oils and repacking of greases will involve connecting pumps to 180 kg steel drums and pumping either to an enclosed blending/packaging line or directly to containers. Some exposure may be possible while connecting and disconnecting transfer lines or during cleaning and maintenance of equipment.

The gear oils and greases can be used in a wide variety of industrial machinery and the greases can be used to grease gears in open and closed gearboxes as well as wire ropes. Oil transfer would be by pump or funnel and grease is applied by cartridge, grease gun or by hand. There is clearly potential for spillage although the spill is unlikely to be widely dispersed. The low concentration of the notified chemical in the imported products means that exposure of fitters will be low.

9.2.2. Public health – exposure assessment

The imported products containing the notified chemical will not be sold to the public and, therefore, the sole opportunity for public exposure may be a transport accident where containers are ruptured. Therefore, public exposure to the notified chemical is expected to be low.

9.2.3. Human health - effects assessment

Additiv 104, containing more than 50% notified chemical, was used for a number of toxicological endpoints. Additiv 104 was found to exhibit low acute oral and dermal toxicity in rats, was a moderate skin irritant and a slight eye irritant in rabbits and was neither mutagenic in bacteria nor clastogenic in mammalian cells in vitro. Evidence of skin sensitisation was found in a guinea pig maximisation test. The 28-day oral repeat dose study in rats suggested the notified chemical had mainly local (probably irritant) effects on the forestomach with a NOEL of 200 mg/kg/day bw.

9.2.4. Occupational health and safety – risk characterisation

Although exposure of workers to greases and/or oils can be relatively frequent, the risk of skin irritation is limited by the low concentration of the notified chemical in the imported products. At a concentration of less than 2%, the notified chemical would render the products hazardous according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). According to the sensitisation study products containing the notified chemical at 0.05% would be classified as skin sensitisers. Therefore, there is a risk of skin sensitisation for workers involved in formulating gear oils, repacking imported products and in application of oils and greases. To minimise this risk protective clothing including a PVC or nitrile apron, PVC or nitrile gloves, safety glasses or faceshield and respirator where ventilation is inadequate and

vapours or mists are generated are recommended. In addition, the practice of using unprotected hands to apply grease should be discontinued for these products.

9.2.5. Public health – risk characterisation

There should be little public exposure to the notified chemical and the risk should, therefore, be low.

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
- R43 May cause sensitisation by skin contact

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio 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 High Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health under the conditions of use described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of a typical 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, 1994a). 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 labels for typical product containing the chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). 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:

  – R43 May cause sensitisation by skin contact
  – R38 Irritating to skin
  – S24/25: Avoid contact with skin and eyes
  – S37: Wear suitable gloves

- The notified chemical should be classified and labelled as follows under the OECD (2002) Globally Harmonised System for the Classification and Labelling of Chemicals: Acute Hazard Category 3: Harmful to aquatic organisms and Chronic Hazard Category 3: Harmful to Aquatic Life with long Lasting Effects

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 0.05%, R43
  - ≥ 20%, R38, R43

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during reformulation of the notified chemical:
  - Prevent splashes and spills

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during formulation of the gear oil concentrate:
  - Chemical resistant gloves, protective overalls, and goggles/faceshield.

- Copies of 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 not be disposed of into drains or onto the ground, but should be recycled or disposed of in accordance with State EPA regulations. Do not allow spills or used lubricants to enter drains, sewers, water courses or soil.

Emergency procedures

- Spills/release of the notified chemical should be contained with an absorbent, inert material (soil, sand, sawdust, vermiculite) and collected in sealable, labelled containers for disposal.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - The concentration of the notified chemical exceeds 2% in the final products
  - The final products become available for use by the public

(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.

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