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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME  
(NICNAS)**

**FULL PUBLIC REPORT**

**Propanoic acid, 3-[[bis(2-methylpropoxy)phosphinothioyl]thio]-2-methyl-**

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**Director  
Chemicals Notification and Assessment**

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## FULL PUBLIC REPORT

<b>Propanoic acid, 3-[[bis(2-methylpropoxy)phosphinothioyl]thio]-2-methyl-</b>
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### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Ciba Specialty Chemicals (ACN 005 061 469) of 235 Settlement Rd Thomastown VIC 3074.

NOTIFICATION CATEGORY

Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

CEC/519

NOTIFICATION IN OTHER COUNTRIES

Italy: notification number 00-37-1586-01

### 2. IDENTITY OF CHEMICAL

CHEMICAL NAME

Propanoic acid, 3-[[bis(2-methylpropoxy)phosphinothioyl]thio]-2-methyl-

OTHER NAME(S)

3-(diisobutoxy-thiophosphorylsulphanyl)-2-methyl-propionic acid

MARKETING NAME(S)

Irgalube 353; CG 37-1586; TKA 40200.

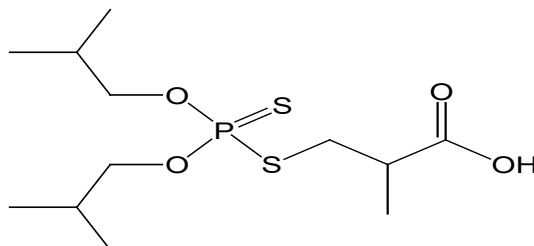
CAS NUMBER

268567-32-4

MOLECULAR FORMULA

C<sub>12</sub>H<sub>25</sub>O<sub>4</sub>PS<sub>2</sub>

STRUCTURAL FORMULA



MOLECULAR WEIGHT  
328.43

SPECTRAL DATA  
Ultraviolet/Visible, infrared and nuclear magnetic resonance spectra were provided.

### 3. COMPOSITION

DEGREE OF PURITY  
86%

#### HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

<i>Chemical Name</i>	methacrylic acid		
<i>CAS No.</i>	79-41-4	<i>Weight %</i>	0.3
<i>Hazardous Properties</i>	Corrosive; mixtures classified as irritation to eyes and skin when containing methacrylic acid at concentrations above 2% (NOHSC, 1999a); NOHSC exposure standard 20 ppm (TWA) (NOHSC, 1995).		

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

#### OTHER IMPURITIES

<i>Chemical Name</i>	3-[3-(diisobutoxy-thiophosphorylsulfanyl)-2-methyl-propionylsulfanyl]-2-methyl-propionic acid		
<i>CAS No.</i>		<i>Weight %</i>	6.8
<i>Chemical Name</i>	3-(diisobutoxy-thiophosphorylsulfanyl)-2-methyl-propionic acid isobutyl ester		
<i>CAS No.</i>		<i>Weight %</i>	4.4
<i>Chemical Name</i>	Designated as CG 39-0528		
<i>CAS No.</i>		<i>Weight %</i>	0.1
<i>Chemical Name</i>	Sum of 5 unknown.		
<i>CAS No.</i>		<i>Weight %</i>	2.1

ADDITIVES/ADJUVANTS  
None.

### 4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS  
The notified chemical will be imported neat in 50 or 216 kg fixed-head steel drums.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	2 - 4	4 - 8	4 - 8	4 - 8	4 - 8

USE  
Anti-wear additive in lubricants and hydraulic fluids.

## 5. PROCESS AND RELEASE INFORMATION

### 5.1. Distribution, Transport and Storage

PORT OF ENTRY  
Melbourne, Victoria.

IDENTITY OF MANUFACTURER/RECIPIENTS  
One user in Melbourne.

#### TRANSPORTATION AND PACKAGING

Transportation is expected to be by road and rail. The notified chemical is to be imported neat in 50 or 216 kg fixed-head steel drums, blended into lubricants and hydraulic fluids and filled into small (< 50 L) plastic containers and 200 L plastic or metal drums.

### 5.2. Operation Description

Blending of the notified chemical into lubricants or hydraulic fluids is accomplished either by decanting under local exhaust ventilation into a blending vessel or pumping via a closed system. If decanting is used, the drum bung is removed and replaced by a control valve prior to raising the drum by a foot-powered drum tilter over the blending vessel manhole. Each emptied drum is rinsed with base fluid and the fluid added to the blending vessel. After the addition of other ingredients, blending takes place with the removal of small samples for QC checking. Final products are then filled into packaging via a closed system under local exhaust ventilation.

Use in greases or transmission oil is not envisaged. The notified chemical is expected to be used in turbine and circulating oils, compressor oils, hydraulic fluids, gear oils and possibly automotive gear oils and marine lubricants at a concentration between 0.1% and 0.5%. The hydraulic fluids, which will comprise approximately 40% of all applications, may be used in the steel industry, mining, agricultural, automotive and manufacturing industries. Typically, the oils and hydraulic fluids will have a long service life and may be filled to machinery via automatic systems, particularly when the machinery is first manufactured.

### 5.3. Occupational exposure

#### *Number and Category of Workers*

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Blending operator	1	< 1 hour/day	25 days/year
QC Technician	1	< 1 hour/day	25 days/year
OEM Applicator	20	< 1 hour/day	50 days/year
Maintenance operator	50	< 1 hour/day	50 days/year

#### *Exposure Details*

Inhalation exposure is not expected given the low vapour pressure of the notified chemical. Dermal or to a lesser extent ocular exposure appears to be controlled during decanting by the use of a control valve and pumping via a closed system. Some minor spillage may be expected and worker exposure is controlled by the use of long PVC or nitrile gloves, eye protection and overalls. For the QC technician the possibility of exposure during removal of small samples is possible and is controlled by use of the same personal protective equipment.

The greatest potential for exposure exists for machine maintenance workers as residues will remain in lines and associated devices. However, breakdowns should be relatively infrequent and maintenance workers will be wearing gloves to prevent dermal exposure.

Workers involved in filling oils or hydraulic fluids to machinery are exposed to the notified chemical at a maximum concentration of 0.5%. Typically gear oils or hydraulic fluids would be added when the machinery is manufactured and only small amounts would be added over its life. Complete change of oil or fluid would be infrequent.

### 5.4. Release

RELEASE OF CHEMICAL AT SITE

The notifier does not anticipate release of the chemical during handling or transport from the port to the customer site except in the event of an accident. Such spills are not expected given the sturdiness of the fixed-head steel drums.

Some release of the notified chemical at the blending site is possible as a result of incidental spills or leaks and during blending and machine maintenance. In general, however, fluid remaining in pumping lines and equipment is usually purged and recycled in the next batch of product. The notifier estimates that waste generated during formulation will not be more than 0.2 L per tonne of the imported substance per year. Given a maximum import volume of 8 tonnes, this equates to about 1.6 L of notified substance generated as waste during formulation.

In the event of accidental release, the MSDS recommends the substance be taken up with absorbent, inert material and the material placed in sealable containers for disposal in accordance with State regulations by High Temperature Incineration.

The notifier has indicated that the empty import containers will be rinsed with base fluid and the rinsed material added back to the blending vessel so that there will be virtually no notified substance left in the drums. The drums are then sent to accredited drum reconditioners for recycling.

#### RELEASE OF CHEMICAL FROM USE

Release of the notified chemical contained in the lubricant and hydraulic fluid at end use could occur in several ways, including through leakages from mobile machinery during operation, through spills during oil changes, and from improper disposal of used oils following machinery oil changes. However, it is difficult to estimate the amount of oil released to the environment through these routes. The amount of lubricant oil resurfacing as used oil will depend on the type of application, with some applications resulting in all of the used oil being generated as waste, and others resulting in all the oil being burned or lost through leakage (Macpherson, 1997). Because the lubricant will be housed in sealed units which are changed at a frequency of 3 to 5 years, the notifier expects release through leakages from mobile machinery will be insignificant.

The fate of used oils in Australia has been the subject of a number of surveys. Australian Institute of Petroleum surveys (AIP, 1995; 1998) indicated that at least 60% of all used oils generated are collected for recycling to be resold mainly as fuel oil. The fate of the remaining 40% of used oil could include a substantial portion being reused especially in the mining, agricultural and transport sectors. The AIP 1998 report indicated no evidence that bulk used oil was being dumped, but admitted there was some uncertainty as to the fate of 40% of used oil generated, but not collected for recycling.

Release through improper disposal is expected to be minimal for lubricant sold to the industrial market, where most used oils are disposed of by recycling or refining. Given the industrial applications, the notifier expects that almost 100% of fluids containing the notified chemical will be sent for recycling.

#### **5.5. Disposal**

The MSDS recommends the notified chemical be disposed of by high temperature incineration and according to State Regulations.

#### **5.6. Public exposure**

There is potential for public exposure to the notified chemical in an accidental spillage during transportation. In the event of spillage, the spills should be soaked up with inert material (e.g. sand, silica gel, acid binder, universal binder, sawdust), and collected into tightly sealed and properly labelled containers for incineration or landfill. The spills should not be flushed into surface water, sanitary sewer or ground water system. In the formulation plant, washing from purging of blending and packaging equipment with a base fluid will be recycled into the next batch of the product, and no more than 0.2 L per tonne of the notified chemical per year will be produced as waste for disposal. Empty drums will be rinsed with base fluid and the rinses pass to the blending process, and the rinsed drums are sent to an accredited drum reconditioner. Used oils will be recycled and none should be disposed of to sewer or landfill. In case of the oil disposed of unlawfully to landfill, the leachability to ground water in landfill would be expected to be negligible as the hydrophobic nature of the notified substance would indicate strong absorption to soils.

The notified substance will be incorporated into lubricating oils and hydraulic fluids at low concentrations (0.1 - 0.5%). The end use lubricants will be predominantly gear oils used industrially and the public exposure should be low.

## 6. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance at 20°C and 101.3 kPa** Colourless to yellow liquid.

**Melting Point/Freezing Point** - 45°C

METHOD OECD TG 102 Melting Point.  
Remarks Freezing point was determined visually as a sudden increase in viscosity.  
TEST FACILITY RCC (2000a).

**Boiling Point** > 175°C at 101.3 kPa

METHOD OECD TG 103.  
Remarks The substance decomposed at 175°C.  
TEST FACILITY Solvias (2000a).

**Density** 1111 kg/m<sup>3</sup> at 20°C

METHOD OECD TG 109.  
Remarks None.  
TEST FACILITY RCC (2000b).

**Vapour Pressure** 1.3 x 10<sup>-8</sup> kPa at 25°C.

METHOD OECD TG 104 Vapour Pressure.  
Remarks The gas saturation HPLC method was used to determine the vapour pressure of the notified chemical (90% purity), at three different gas flow rates. The experimental results indicate the substance is only very slightly volatile.  
TEST FACILITY Solvias (2000b).

**Water Solubility** 7.8 mg/L at 20°C

METHOD OECD TG 105 Water Solubility.  
Remarks Following a preliminary test using a simple flask method, excess amounts (25 mg) of test substance were added to 25 mL water, and the 6 test flasks shaken for 24, 48, and 72 hours, respectively. The flasks were equilibrated for 24 hours and the supernatant solution was filtered and centrifuged prior to HPLC analyses to quantify the concentrations of test substance dissolved in solution. The concentrations in the 6 replicate samples determined after 24, 48, and 72 hours differed by less than 30%, indicating the test was valid. The test results indicate the notified chemical is slightly soluble in water.  
TEST FACILITY RCC (2000c).

### Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.

<i>pH</i>	<i>T</i> (°C)	<i>t</i> <sub>½</sub>
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4	25	111 days
	50	stable
9	50	stable

Remarks Preliminary hydrolysis testing was carried out at pH 4, 7, and 9 and at a temperature of 50°C over a 5-day test period. The test substance was found to be stable at pH 7 and 9, and hence no further testing was conducted. At pH 4, 17% of the test material was hydrolysed after 5 day, and so further testing was performed at temperatures of 25, 50, 70, 80°C. These results indicate the notified chemical only slightly hydrolyses at pH < 4.

TEST FACILITY RCC (2000d).

**Partition Coefficient (n-octanol/water)** log Pow at 20°C = 3.9

METHOD OECD TG 117.

EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks To prepare the stock solution, an amount of test material was dissolved in 20 mL acetonitrile and the solution diluted to the required concentration. The HPLC retention times of the test substance (3 reps) were compared against those of the 6 reference substances (6 reps each). The log Pow was calculated using a regression curve. The results indicate the notified chemical has a strong affinity to lipids.

TEST FACILITY RCC (2000e).

**Adsorption/Desorption** log K<sub>oc</sub> = >3.14.

METHOD OECD TG 106.

Remarks The adsorption coefficient was determined using regression equations based on the water solubility and the molecular weight of the notified chemical. These were as follows:

Regression I: log K<sub>oc</sub> = -0.55log S + 3.64 (S = water solubility in mg/L)

Regression II: log K<sub>oc</sub> = -0.54log S + 0.44 (S in mole fraction)

Regression III: log K<sub>oc</sub> = -0.557log S + 4.277 (S in mmoles/L)

An estimation was also performed based on the partition coefficient and using the regression equation: log K<sub>oc</sub> = 0.544logPow + 1.377. The results indicate the notified chemical has low mobility in soils.

TEST FACILITY RCC (2000f).

**Dissociation Constant** pK<sub>a</sub> = 4.3

METHOD OECD TG 112.

Remarks The dissociation constant was estimated using linear free energy relationships according to the Hammett and Taft equations derived for aromatic and aliphatic systems, respectively. The results indicate the notified chemical will be dissociated in an aqueous environment in the pH range 5 – 8. The calculation was based on dissociable functional groups. The notified chemical has one site which can be protonated. The acid pK<sub>a</sub> based on Taft is 4.3.

TEST FACILITY RCC (2000g)

**Flash Point** 141.5°C at 101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.

Remarks None.

TEST FACILITY Institute of Safety and Security (1999a).

**Pyrophoric properties** Not pyrophoric.

METHOD EC Directive 92/69/EEC A.13 Pyrophoric properties of solids and liquids.

Remarks No ignition or charring within 5 minutes.

TEST FACILITY Institute of Safety and Security (1999b).



**Autoignition Temperature** 390°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.  
Remarks None.

**Explosive Properties** None.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.  
Remarks No explosive effects: thermally, mechanically or via friction.  
TEST FACILITY Institute of Safety and Security (1999c).

**Reactivity** No oxidising.

Remarks None.  
TEST FACILITY Institute of Safety and Security (1999d).

**Fat (or n-octanol) Solubility** 1031 g/kg fat at 37°C.

METHOD OECD TG 116.  
Remarks Following a preliminary test, which showed complete dissolution of 10 g of the test item in 10 g of fat, the miscibility of the test substance in fat was determined visually at 3 different ratios (1:20, 1:1, 20:1). The concentration in solution was determined by HPLC. The test material was miscible in all proportions.  
TEST FACILITY RCC (2000h).

**Surface Tension** 42.6 N/m at 20°C

METHOD OECD TG 115.  
Remarks The notified chemical is surface active.  
TEST FACILITY RCC (2000i).

## 7. TOXICOLOGICAL INVESTIGATIONS

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test/non-adjuvant test.	evidence of sensitisation
Rat, oral repeat dose toxicity - 28 days.	NOEL = 20 mg/kg/day bw
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vivo micronucleus test	non genotoxic

### 7.1. Acute toxicity – oral

TEST SUBSTANCE CG 37-1586 (TKA 40200) (notified chemical).

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.  
Species/Strain Rat/Wistar  
Vehicle PEG 300

#### RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	3 males	2000	0/3
2	3 females	2000	1/3

LD50 > 2000 mg/kg bw

Signs of Toxicity Ruffled fur, ventral position and convulsions in the single female found dead 3 hours after treatment. Possibly due to gavage error.

Effects in Organs None.

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

TEST FACILITY RCC (2000j).

### 7.2. Acute toxicity - dermal

TEST SUBSTANCE CG 37-1586 (TKA 40200).

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.  
Species/Strain Rat/Wistar  
Vehicle None.  
Type of dressing Semi-occlusive.

#### RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	3 males	2000	0/3
2	3 females	2000	0/3

LD50 > 2000 mg/kg bw

Signs of Toxicity - Local None.

Signs of Toxicity - Systemic None.

Effects in Organs None.

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

TEST FACILITY RCC (2000k).

### 7.3. Acute toxicity - inhalation

No data provided.

### 7.4. Irritation – skin

TEST SUBSTANCE CG 37-1586 (TKA 40200).

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.  
Species/Strain Rabbit/New Zealand White  
Number of Animals 3  
Vehicle None.  
Observation Period 3 days.  
Type of Dressing Semi-occlusive.

#### RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	0	0	0	0	0	0
<i>Oedema</i>	0	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 non-irritating to skin.

TEST FACILITY RCC (2000l).

### 7.5. Irritation - eye

TEST SUBSTANCE CG 37-1586 (TKA 40200).

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.  
Species/Strain Rabbit/New Zealand White  
Number of Animals 3  
Observation Period 21 days.

#### RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	2	1.33	1.33	2	21 days.	1
<i>Conjunctiva: chemosis</i>	2	1.33	1	2	72 hours.	0
<i>Corneal opacity</i>	1	1.33	1	2	21 days.	1
<i>Iridial inflammation</i>	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 (2000m).

## 7.6. Skin sensitisation

TEST SUBSTANCE	CG 37-1586 (TKA 40200).		
METHOD	OECD TG 406 Skin Sensitisation – Maximisation test.		
Species/Strain	Guinea pig/Himalayan spotted.		
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 50% concentration, the lowest used, gave a reading of 2 topical: 50%		
MAIN STUDY			
Number of Animals induction phase	Test Group: 10 Induction Concentration: intradermal injection: 50% topical application: 50%	Control Group: 5	
Signs of Irritation	No signs in control group after epidermal induction with PEG 400. In the test group discrete/patchy erythema was observed in all animals at the 24-hour reading and in 8 out of 10 animals at the 48-hour reading.		
CHALLENGE PHASE			
1 <sup>st</sup> challenge	topical application: 50%		

### RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions afte challenge:</i>	
		<i>24 h</i>	<i>48 h</i>
<i>Test Group</i>	50%	7/10	7/10
<i>Control Group</i>	50%	0/5	0/5

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

TEST FACILITY RCC (2000n).

## 7.7. Repeat dose toxicity

TEST SUBSTANCE	CG 37-1586 (TKA 40200).		
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.		
Species/Strain	Rat/Wistar.		
Route of Administration	Oral – gavage.		
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: extra control and high dose groups had a 14-day recovery period		
Vehicle	PEG 300		

### RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw/day</i>	<i>Mortality</i>
I (control)	5/sex	0	None.

*Clinical Observations*  
No remarkable clinical signs or effects on food consumption or body weight.

## Clinical Chemistry

Higher albumin levels and albumin/globulin ratios were found in high dose animals of both sexes, higher total protein in high dose females. After recovery the elevated albumin levels persisted in males. All changes were within the 95% confidence limits of the historical control data.

### Haematology

Plasma haemoglobin concentration and haematocrit were lower in high dose animals and red blood cell count was lower in high dose females. The toxicological significance of these findings is uncertain.

High dose animals exhibited a prolonged activated partial thromboplastin time, females had a shorter thromboplastin time and males had a higher platelet count. All changes were within the 95% confidence limits of the historical control data. Prolonged activated PTT and platelet counts reached statistical significance in high dose recovery group males.

Ketone was present in mid dose females and high dose animals of both sexes and was considered to be related to the adaptive changes in lipid metabolism.

High dose females exhibited higher specific gravity and high dose animals of both sexes had slightly lower urine production. These were within the 95% confidence limits of historical control data and may indicate a possible change in the ability to concentrate urine.

High dose animals exhibited higher absolute and relative liver weights. These effects persisted in males at the end of the recovery period and were considered to be treatment related yet adaptive.

High dose animals exhibited higher kidney/body weight ratios, higher absolute kidney weights and kidney to brain weight ratio. Mid dose males also exhibited an elevated kidney/body weight ratio.

The No Observed Effect Level (NOEL) was established as 20 mg/kg bw/day in this study, based on elevated kidney/body weight ratio in males.

TEST FACILITY RCC (2000o).

TEST SUBSTANCE CG 37-1586 (TKA 40200).

METHOD OECD TG 471 Bacterial Reverse Mutation Test.

Species/Strain	<i>S. typhimurium</i> : TA1538, TA1535, TA1537, TA98, TA100. <i>E. coli</i> : WP2 uvrA.
Metabolic Activation System	Rat liver S9 microsomal fraction (phenobarbital/β-naphthoflavone induction).
Concentration Range in Main Test	a) With metabolic activation: 33 - 5000 µg/plate. b) Without metabolic activation: 33 - 5000 µg/plate.
Vehicle	DMSO.

#### RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1	> 5000	> 5000	-	-
Test 2	> 5000	> 5000	-	-
<i>Present</i>				
Test 1	> 5000	> 5000	-	-
Test 2	> 5000	> 5000	-	-

**Remarks Results** Toxicity, detected as a reduction in the number of spontaneous mutants per plate, was observed in experiment I with TA 1537 (+S9) at 5000 µg/plate. In experiment II, toxicity was observed in strains TA 1535 and TA 1537 both without S9 (2500, 5000 µg/plate) and with S9 (TA 1535: 1000 - 5000 µg/plate; TA 1537: 2500, 5000 µg/plate). No substantial treatment related increase in the number of revertant colonies was observed.

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

**TEST FACILITY** RCC (2000p).

#### 7.9. Genotoxicity – in vivo

**TEST SUBSTANCE** CG 37-1586 (TKA 40200).

**METHOD** OECD TG 474 Mammalian Erythrocyte Micronucleus Test.  
**Species/Strain** Mouse/NMRI.  
**Route of Administration** Oral – gavage.  
**Vehicle** Corn oil.

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Sacrifice Time hours</i>
1	5/sex	450	24
2	“	900	24
3	“	1800	24, 48

#### RESULTS

**Doses Producing Toxicity** 1800 mg/kg bw  
**Genotoxic Effects** None.

**CONCLUSION** The notified chemical was not clastogenic in this in vivo micronucleus test under the conditions of the test.

**TEST FACILITY** RCC (2000q).

## 8. ENVIRONMENT

### 8.1. Environmental fate

#### 8.1.1. Ready biodegradability

##### TEST SUBSTANCE

##### METHOD

OECD TG 301 B Ready Biodegradability: CO<sub>2</sub> Evolution (Modified Sturm) Test.

Inoculum Activated sludge from domestic wastewater treatment plant.

Exposure Period 28 days

Auxiliary Solvent None

Analytical Monitoring Analyses of inorganic carbon.

Remarks - Method The study involved exposing micro-organisms from activated sludge to 34 mg/L of the test substance. Nine test vessels were set up comprising 2 replicates each of the test item, inoculum control, procedure control (containing sodium benzoate as a reference substance), and abiotic control (poisoned with mercury dichloride), and 1 replicate used as a toxicity control, containing only the test item and reference substance.

##### RESULTS

<i>Test substance</i>		<i>sodium benzoate</i>	
<i>Day</i>	<i>% degradation</i>	<i>Day</i>	<i>% degradation</i>
10	<10	10	70
28	<10	28	83

##### Remarks - Results

The test item was degraded by < 5% over the 28-day period, indicating the test substance is not readily biodegradable. By comparison, the reference substance was degraded by 70% within 7 days indicating the test micro-organisms and test system were viable. There was no degradation of the control, containing the test item and the poisoned test media, indicating no abiotic degradation occurred. In addition, the test item had no inhibitory effect on activated sludge micro-organisms, which degraded the reference item by 41% within 14 days, indicating the substance is not toxic to micro-organisms.

##### CONCLUSION

The notified chemical is not readily biodegradable.

##### TEST FACILITY

RCC (2000r).

#### 8.1.2. Bioaccumulation

No bioaccumulation test data were provided in the notification dossier. The high fat solubility and low molecular weight suggest the chemical has the potential to bioaccumulate. However, under normal usage limited aqueous exposure is expected.

### 8.2. Ecotoxicological investigations

#### 8.2.1. Acute toxicity to fish

##### TEST SUBSTANCE

CG 37-1586 (TKA 40200)

##### METHOD

OECD TG 203 Fish, Acute Toxicity Test –Static Test.

## RESULTS

LC50	38 mg/L at 96 hours (C.I. = 27-54 mg/L)
NOEC (or LOEC)	27 mg/L at 96 hours.
Remarks – Results	There were no fish mortalities or abnormal effects in the control or in fish exposed to test concentrations of up to and including 27 mg/L. All fish exposed to test concentrations of 54 mg/L and to the undiluted filtrate were dead after 24 hours of exposure. All fish exposed to the undiluted filtrate showed intoxication symptoms 2.5 hours after introduction to the test medium. This included lying on their side or back at the bottom of the tank and tumbling during swimming.

### 8.2.2. Acute/chronic toxicity to aquatic invertebrates

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*STD/1013*



measured at the start of the test.

## RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
Control	-	20	0	0
1:16	n.a.	20	0	0
1:8	n.a.	20	0	0
1:4	24	20	0	0
1:2	49	20	0	7
Undiluted filtrate	100	20	9	20

LC50 53 mg/L at 48 hours (C. I. = 44-62 mg/L)

NOEC (or LOEC) 24 mg/L at 48 hours

Remarks - Results The test results showed that 45% of daphnids exposed to the undiluted filtrate were immobilised after 24 hours while 100 % were immobilised after 48 hours, and 35% of daphnids exposed to concentrations of 49 mg/L were immobilised after 48 hours.

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

TEST FACILITY RCC (2000t).

### 8.2.3. Algal growth inhibition test

TEST SUBSTANCE CG 37-1586 (TKA 40200)

METHOD OECD TG 201.

Species *Scenedesmus subspicatus*

Exposure Period 72 hours

Concentration Range 0, 6.25, 12.5, 25, 50, and 100 mg/L

Nominal

Concentration Range Actual Between 99 to 100% nominal for the concentrations tested.

Actual

Auxiliary Solvent None

Water Hardness 24 mg CaCO<sub>3</sub>/L

Analytical Monitoring Test concentrations using HPLC

Remarks - Method Algae were exposed to the test material at dilution concentrations of 0, 1:16, 1:8, 1:4, 1:2, and undiluted filtrate containing 100 mg/L. To prepare the stock solution, the test substance was dissolved in test water by 96 hours of intense stirring at room temperature. The dispersion was then filtered (pore size = 0.45 µm) prior to dilution to the required test concentrations. Test concentrations were measured at the start and end of the test in the test medium containing dilution factors of 1:4 and 1:2. Results showed the concentration of the test substance at the end of the test ranged from 99 to 100% of the values measured at the start of the test. The EC<sub>50</sub> endpoints were calculated using by Probit Analysis.

## RESULTS

72 hour Endpoints	Biomass mg/L	Growth mg/L
EC <sub>50</sub>	79	>100
NOEC	28	28

Remarks - Results The test substance had a slight inhibitory effect on the biomass and growth rate of green algae after 72 hours of exposure at measured

concentrations of 55 mg/L. At measured concentrations of 112 mg/L 87% inhibition in cell densities was observed compared to the control. Microscopic examination of the algal cells after 72 hours showed no differences in the shape and size between the algae cells growing in test concentrations of 112 mg/L and those growing in the control.

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

TEST FACILITY RCC (2000u).

#### 8.2.4. Inhibition of microbial activity

TEST SUBSTANCE CG 37-1586 (TKA 40200)

METHOD OECD TG 209.

Inoculum Activated sludge from wastewater treatment plant

Exposure Period 3 hours

Concentration Range 0, 6.25, 12.5, 25, 50 and 100 mg/L

Nominal

Remarks – Method Sewage micro-organisms were exposed to five concentrations of the notified chemical, and two controls containing no test material. In addition, they were exposed to three concentrations (5, 16 and 50 mg/L) of a reference substance, 3,5-dichlorophenol. The test media was prepared by adding the test material directly to deionized water, which underwent 15 minutes of ultrasonic treatment, and 24 hours of intense stirring at room temperature. At the two highest concentrations, some of the test substance was observed suspended in the test media, indicating these concentrations were above the water solubility limit. The pH values of the test media with nominal concentrations of 25, 50, and 100 mg/L of test substance were in the range of 3.8-4.2, and therefore were adjusted to 6.9-7.3 with sodium hydroxide.

#### RESULTS

IC50 > 100 mg/L

NOEC > 100 mg/L

Remarks – Results No significant inhibitory effects on the respiration rates of activated sludge micro-organisms was observed after the 3 hour incubation period at exposure concentrations of up to and including 100 mg/L of the test substance.

CONCLUSION The test substance is not toxic to sewage micro-organisms (Mensink *et al.* 1995).

TEST FACILITY RCC (2000v).

## 9. RISK ASSESSMENT

### 9.1. Environment

#### 9.1.1. Environment – exposure assessment

The amount of notified chemical making its way to terrestrial or aquatic environments during its use is difficult to determine. Release of the notified chemical at end use could occur in through leakages or spills of the lubricant and hydraulic fluid from mobile machinery during operation or oil changes, and through improper disposal of used oils following machinery oil changes. The notifier has suggested the potential fate of the notified substance as follows: 25% burned in

engines, 20% re-refined, 17% burned in fuel oil, 4% incinerated, and the remaining 34% unaccounted for. If we assume the 34% of the unaccounted used oil is disposed of improperly, this would equate to release of 2.72 tonnes of notified chemical each year.

Use of the products containing the notified chemical are expected to occur nationwide, therefore release will be diffuse. As such, the exposure assessment will focus on continental release into the aquatic environment. We have calculated a very worst case scenario Predicted Environmental Concentration (PEC) for the aquatic environment of  $2.48 \times 10^{-3}$  mg/L, which assumes the maximum 2.72 tonnes of notified chemical is directly discharged into the sewer each year. We have also assumed discharge occurs over 365 days, and that water usage is 150 L of water per day by a population of 20 million people.

The PEC does not take into account removal from the aquatic environment by adsorption. The chemical is not volatile, is only slightly soluble in water, and has a strong affinity to lipids, indicating that in the sewer, the chemical will partition mainly in sludge. It is expected that most sewage sludge will be disposed of to land or landfill, and that most of the chemical would ultimately end up in the soil rather than in the aquatic environment. In soil environments, the log K<sub>oc</sub> indicates that the chemical will be immobile.

At least 50% of the notified chemical could be burned either during use or disposal by incineration. Incineration would destroy the notified chemical producing water vapour and oxides of carbon, sulphur and phosphorus.

The notified chemical is not readily biodegraded and therefore could persist for some time in the environment. The chemical's high partition coefficient and fat solubility indicate the substance could cross biological membranes and bioaccumulate.

#### **9.1.2. Environment – effects assessment**

The notifier supplied acute ecotoxicity test reports for studies conducted against fish, Daphnia, Green algae and sewage micro-organisms. The data indicate the notified chemical is slightly toxic to fish, Daphnia, and algae, but is not toxic to sewage microbes.

A predicted no effects concentration (PNEC) can be determined when at least one acute LC<sub>50</sub> for each of the three trophic levels is available (ie. fish, Daphnia, algae). The PNEC is calculated by taking the LC<sub>50</sub> value of the most sensitive species, and dividing this value by an assessment safety factor. The most sensitive species was *Daphnia magna* with a 96 hour LC<sub>50</sub> of 24 mg/L. Using a worst case scenario safety factor of 100 (OECD), the PNEC<sub>aquatic</sub> is 0.24 mg/L.

#### **9.1.3. Environment – risk characterisation**

We have calculated the worst case scenario daily PEC of the notified chemical for the aquatic environment to be approximately  $2.48 \times 10^{-3}$  mg/L if 34% were discharged into the domestic sewer in a diffuse manner. Using the LC<sub>50</sub> of the most sensitive species, Daphnia, and a safety factor of 100, the PNEC<sub>aquatic</sub> is 0.24 mg/L. This gives a PEC/PNEC ratio of 0.01, which is significantly less than one, and indicates no immediate concern toward aquatic organisms. However, given that the chemical will be used in industrial applications, where it is expected that 100% of the lubricant will be recycled, the actual PEC is expected to be many orders of magnitude lower than the worst case value.

The calculated PEC value assumes a very worst-case situation of improper disposal and no losses or adsorption in the sewer. However, under normal usage and proper disposal, release of the chemical into the sewer is not anticipated. Release through improper disposal is expected to be minimal for lubricant sold to the industrial market, where most used oils are disposed of by recycling, burning or refining. In addition, owing to the chemical's low volatility, low water solubility, and strong affinity to lipids, most of the chemical finding its way into the environment would ultimately end up in the soil rather than in the aquatic environment, due to its partition mainly into organic phases. Waste sludge is usually used in land farming or disposed of to landfill.

In soil environments, the log K<sub>oc</sub> indicates that the chemical will be immobile. While not

readily biodegraded by sewage micro-organisms, the substance is likely to be slowly degraded in soil environments by soil microbes and abiotic processes.

## **9.2. Human health**

### **9.2.1. Occupational health and safety – exposure assessment**

Exposure to the notified chemical during transport and storage should only occur in the event of rupture of the containers. However, this is likely to be infrequent.

The low vapour pressure of the notified chemical should preclude inhalation exposure during transfer to the blending vessel and packing the finished lubricants and hydraulic fluids into end use containers. Nevertheless, local exhaust ventilation is provided over the blending vessel and during packing off should further reduce possibility of exposure to aerosols and vapours. Following incorporation of the notified chemical into end use products at a maximum concentration of 0.5% atmospheric levels should be negligible.

Dermal exposure during addition of the notified chemical to the blending vessel is controlled by the use of a control valve during decanting or a closed system during pumping. Exposure to minor drips and spills is possible during transfer and QC testing and is controlled by the use of long PVC or nitrile gloves, eye protection and overalls. Similar potential for exposure exists during machine maintenance and incorporation of drum residues into the blend and is controlled in the same way by personal protective equipment. Once the notified chemical is incorporated into end use products it is at a low concentration and exposure should be negligible.

### **9.2.2. Public health – exposure assessment**

The notified chemical will be imported for industrial use only, and be incorporated into lubricating oils and hydraulic fluids at low concentrations. The end use lubricants will be predominantly gear oils used industrially. The public may be exposed to the notified substance during do-it-yourself lubricant changing in a vehicle. However, the exposure is infrequent, transient and at low concentrations, and is predominantly through dermal contact. When used in the proposed manner (with skin and eye protection), the probability of public exposure to the notified chemical will be low, and the resulting health effects will not be significant.

### **9.2.3. Human health - effects assessment**

The notified chemical was of low acute oral and dermal toxicity in rats, was not a skin irritant but was a slight eye irritant in rabbits, and was neither mutagenic in bacteria nor clastogenic in mouse bone marrow cells. It was a skin sensitiser in guinea pigs and exhibited systemic effects at a dose of 500 mg/kg/day bw in a 28-day oral repeated dose study in rats although some of these effects may have been adaptive in nature.

The notified chemical is classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b) and is assigned the risk phrase R43: May cause sensitisation by skin contact.

### **9.2.4. Occupational health and safety – risk characterisation**

The main area of concern for workers is skin sensitisation following contact with the neat chemical. This is likely to occur infrequently to workers involved in addition of the notified chemical to the blending vessel, QC testing and maintenance of the blending equipment. The number of events involving exposure of workers is unknown but is likely to be low. All workers will be wearing personal protective equipment including PVC or nitrile gloves. In these circumstances the risk of skin sensitisation is expected to be low. Once the notified chemical is blended into end use product there should be little risk of skin sensitisation as the products would not be classified as hazardous substances according to NOHSC criteria and would not be assigned the risk phrase R43. Furthermore, most lubricants and hydraulic fluids containing the notified chemical should be loaded automatically to new vehicles and there is little likelihood of worker exposure.

### **9.2.5. Public health – risk characterisation**

There is a low risk of skin sensitisation in members of the public as a result of a transport accident involving drums of the notified chemical. There is also a low risk of skin sensitisation to members of the public arising from industrial use or disposal of the notified chemical in the finished lubricants.

## **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: R43: May cause sensitisation by skin contact.

### **10.2. Environmental risk assessment**

On the basis of the low expected exposure the notified chemical is not considered to pose a risk to the environment based on its reported use pattern and provided the chemical is disposed in the proper manner.

### **10.3. Human health risk assessment**

#### **10.3.1. Occupational health and safety**

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

#### **10.3.2. Public health**

There is Negligible Concern to public health when the notified chemical is used as a component of oils or hydraulic fluids.

## **11. MATERIAL SAFETY DATA SHEET**

### **11.1. Material Safety Data Sheet**

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 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 label for the notified chemical provided by the notifier was 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**

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R43: May cause sensitisation by skin contact.
- Use the following risk phrases for products/mixtures containing the notified chemical:
  - 1%: risk phrase R43

### **CONTROL MEASURES**

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Local exhaust ventilation should be provided at points where the notified chemical is added to blending vessels; closed transfer systems, dry couplings, control valves and drum handling equipment should be used routinely for transfer of the notified chemical to blending equipment.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Long impervious PVC gloves, overalls and safety glasses.

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 recycled through an approved recycler or disposed of by High Temperature Incineration according to State Regulations.

#### Emergency procedures

- Spills/release of the notified chemical should be taken up with an absorbent material and placed in suitable containers for disposal. Spills should not be allowed to enter the drains or waterways.

### 12.1. Secondary notification

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

- (1) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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