File No: NA/636

June 1999

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

PRIOLUBE 3999

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

PRIOLUBE 3999

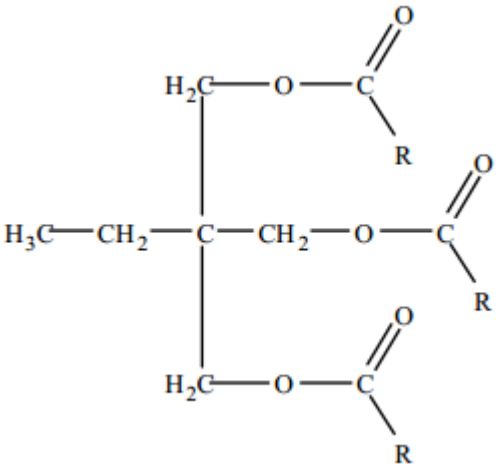
1. APPLICANT

Unichema International Pty Ltd of 14 Woodruff Street PORT MELBOURNE VIC 3207 has submitted a standard notification statement in support of their application for an assessment certificate for Priolube 3999.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	fatty acids, C_{14}-C_{18} and C_{18} unsaturated, branched and linear, esters with trimethylolpropane
Chemical Abstracts Service (CAS) Registry No.:	85005-23-8
Other Name(s):	trimethylolpropane ester of modified fatty acid TMP ester of modified fatty acid
Marketing/Trade Name (Product):	Priolube 3999
Molecular Formula:	$C_9H_{11}O_6$-R_3 (approximately $C_{60}H_{116}O_6$) R (cannot be quantified)

Structural Formula:



Molecular Weight:	935 (approximately)

Method of Detection and Determination: the notified chemical can be detected by infrared (IR), ultraviolet/visible (UV/Vis) and nuclear magnetic resonance (NMR) spectroscopy

Spectral Data: major characteristic IR peaks identified at the following wavelengths: 1 159, 1 378, 1 465, 1 744, 2 855 and 2 926 cm^{-1}

Comments on Chemical Identity:

UV/Vis, IR and ^{1}H NMR spectra have been provided for the chemical. The notified chemical is a triester formed by condensation of trimethylolpropane ($C_6H_{14}O_3$) with a complex mixture of branched and straight chain fatty acids. The notifier provided the following gas liquid chromatography (GLC) analysis of this material, which was indicated to be typical:

Fatty Acid	% Weight		
	Linear	Branched	other
C14	0.3	0.1	–
C16	6.2	4.5	–
C18	2.9	58.6	–
C18:1	4.3	–	–
C18 lactone	–	–	2.4
C20	0.3	9.7	–
C22	0.3	6.8	–
>C22	–	3.6	–

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: yellow liquid with faint odour

Melting Point -25°C to -50°C

Boiling Point: > 240°C

Density: 920 kg/m^3 at 20°C

Vapour Pressure: 6.3 x 10^{-5} kPa at 25°C

Water Solubility: < 0.92 mg/L at 25°C

Partition Co-efficient (n-octanol/water): log P_{ow} > 5.99 (estimated)

Hydrolysis as a Function of pH:	not determined (see comments below)
Adsorption/Desorption:	not determined (see commens below)
Dissociation Constant:	not determined (see comments below)
Flash Point:	250°C (approximately)
Flammability Limits:	not determined
Autoignition Temperature:	> 200°C
Explosive Properties:	from the chemical nature of the notified chemical it is not expected to exhibit explosive properties
Reactivity/Stability:	stable under normal conditions; avoid contact with strong oxidising agents

Comments on Physico-Chemical Properties

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

The water solubility of the notified chemical was determined using the preliminary test outlined in OECD Test Guideline 105. The notified chemical was mixed with double distilled water for 8 days and the resultant phases were observed visually.

No detailed test report was submitted for studies on abiotic hydrolysis because of the low water solubility. The chemical contains an ester group which is inherently susceptible to hydrolytic cleavage, but because of the low water solubility and very hydrophobic nature of the chemical (log P_{ow} > 5.99), intimate contact between the aqueous environment and the susceptible groups is unlikely. Consequently hydrolysis of this group is also unlikely, or would only occur at a very low rate.

The n-octanol/water partition coefficient was estimated from the ratio of the solubility of the new compound in octanol to that in water. A determination of the solubility in octanol gave a value greater than 9.1×10^5 mg/L, while the water solubility was less than 0.92 mg/L, the value of log P_{ow} is estimated to be greater than 5.99.

No report on adsorption/desorption was submitted, but a statement provided by the notifier indicated that the study could not be undertaken because of the low water solubility of the compound, and inadequate sensitivity of existing analytical techniques. Log K_{oc} may be estimated from that of log P_{ow} using the following relationship:- log K_{oc} = 0.81 x log P_{ow} + 0.10 , which gives the estimate log K_{oc} greater than 4.95. This relationship is appropriate for compounds of predominantly hydrophobic nature. The estimated value for log K_{oc} as greater than 4.28 indicates that the chemical would tend to partition into the organic component of

soils and sediments, and become associated with these materials.

The compound contains no functionalities capable of dissociation and consequently dissociation constant data are not relevant to the new chemical.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 92% triester
< 8% diester

Toxic or Hazardous Impurities: none

Non-hazardous Impurities (> 1% by weight): none

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia but will be imported as a raw material and/or in a final product. It is used as a base for production of automotive engine lubricants for four-stroke petrol engines. The concentration of Priolube 3999 in the final product will be in the range 5-20% but may be as high as 80% in some products. Priolube 3999 in motor oil will be available to the general public. It could be used in automotive repair shops and service stations as well as within the D-I-Y market.

It is estimated that 10 to 100 tonnes per annum of the notified chemical will be imported in the first five years.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported into Australia in 190 kg (200 L) mild steel drums. The total import volume will be transported by road to a warehouse for storage prior to transportation to formulation and customer sites. Exposure to waterside, transport or storage workers should only occur in the event of accidental spillage.

Priolube 3999, when imported as a raw material will be formulated (blended) at a maximum of 5 sites. The process typically involves pump transfer of the notified chemical from steel drums to a blending tank where it is mixed with other components to form the final product. The blending is carried out in an open or closed vessel and may vary from one site to another. The blended lubricants will be pumped from the blending tank to containers of varying sizes (20 to 200 kg). After use the drums will be transported to a certified drum cleaning and recycling company where drums will be washed and the effluent treated. The notifier has not indentified the number of personnel exposed to the notified chemical during cleaning and maintenance.

Dermal and ocular exposure may occur during transfer of Priolube 3999 from steel drums to the blending tank resulting from drips and spills that might occur during connecting or disconnecting lines. Inhalation exposure is not expected to occur due to the low vapour

pressure of the notified chemical.

The finished lubricant will contain Priolube 3999 typically at a level of 5 to 20% but up to 80% in some products. The lubricants will be used at garages or at other sites where engines are located. The notifier has indicated that engine mechanics exposed to the finished lubricant containing the notified chemical are expected to wear gloves. However, exposure of the hands may be substantial as it is uncommon for gloves to be worn by mechanics when working with engine oils.

7. PUBLIC EXPOSURE

It is expected that during transport, reformulation, storage and industrial use, exposure of the general public to the notified chemical will be minimal, except in the event of an accidental spill.

Public exposure to the notified chemical is expected to be occasional, but widespread as th automotive oil is to be sold to the public. Public exposure will occur when replenishing automotive oil or undertaking an oil change at home. The most likely routes of exposure are dermal and possibly ocular, as the notified polymer has a low vapour pressure (6.3 x 10-5 kPa at 25°C).

8. ENVIRONMENTAL EXPOSURE

Release

The notifier has indicated that empty drums would be sent to a drum cleaning and recycling facility, where the unused chemical (estimated to be around 4 to 5 L per drum, or approximately 2.5% of imports), will be washed out and the resulting waste treated. It is expected that this waste would be treated in a manner which would recover the unused chemical within a sludge, which would then be either incinerated or placed into landfill.

Some release of the notified material could occur as a result of spills during the reformulation activities, but it is anticipated that these would be small (the notifier estimates < 0.5% waste will be generated during blending), and contained. Collected material would be taken taken to a licensed waste treatment plant where it is anticipated it would be incinerated in accordance with local government regulations.

The vapour pressure of the material is low, so release to the atmosphere is expected to be negligible.

Some release is likely during transfer of the lubricants from containers to engine sumps. If it is assumed that each transfer involves 4 litres of lubricant, then up to 500,000 engine oil changes (using the imported volume of the notified product) could take place throughout Australia each year. The notifier anticipates that on average 20 mL of lubricant - containing 5% of the notified substance - is likely to be either spilt or left as residuals in containers as a result of transfer operations, and consequently around 500 kg (0.5% of import quantity) of the notified material would be released annually via this route.

It is anticipated that 80% of oil changes take place in specialised automotive service centres, where the oil drained from crankcases could be expected to be disposed of via oil recycling or incineration. This accounts for 80 tonnes per annum (assuming 100 tonne annual import) of the notified chemical. Twenty percent of oil transfer operations are expected to be performed by enthusiasts. A recent survey tracing the fate of used lubricating oil (Snow, 1997) indicates that 20% of spent oil removed by enthusiasts is collected for recycling, approximately 25% is buried or tipped into landfill, 5% is disposed of into stormwater drains and the remaining 40% is used in treating fence posts, killing grass and weeds or disposed of in other ways.

Engine lubricants are contained within a closed system, and apart from oil leaks in the engines, very little release of the new chemical is anticipated as a result of normal usage.

Fate

Biodegradation

The notified chemical did not meet the criteria for ready biodegradability in aerobic environments, as determined in a modified Sturm test (OECD Test Guideline 301B). While the test indicated 70% degradation after 28 days this was not achieved within 10 days as required. The material can be classified as inherently biodegradable, and if placed into landfill (for example adsorbed into sawdust after accidental spills) would be slowly degraded through the slow biological and abiotic processes operative in these facilities. These processes would produce carbon dioxide, methane and water.

Soils and Sediments

Leaching from a landfill site is not expected to be significant. The estimated high value of log K_{oc} indicates that the material would not be mobile, but would adsorb to and become associated with the organic component of soils and sediments. Similarly, in the event of accidental release into the water compartment, the chemical is likely to become associated with suspended organic material, and eventually be incorporated into sediments.

Large quantities of material placed into landfill as a result of irresponsible disposal practices would be adsorbed to and become associated with soil material and eventually be slowly degraded as described above.

Incineration

Incineration of waste oil containing the notified material would destroy the substance with evolution of water vapour and oxides of carbon. Sludges from waste treatment plants or oil recycling facilities may also be incinerated.

Bioaccumulation

If released into water, the chemical would become associated with particulate organic matter and sediments because of the high log P_{ow}, log K_{oc} and low water solubility. Under these conditions bioaccumulation in aquatic fauna is unlikely.

9. EVALUATION OF TOXICOLOGICAL DATA

The only toxicological studies submitted for the notified chemical is an acute oral toxicity study in rats. The full study was also provided for acute oral and dermal toxicities in rats, acute dermal irritation and eye irritation in rabbits and skin sensitisation in guinea pig, for

mixed esters of trimethylolpropane with mixed heptanoic acids (RB 105). The remaining data is derived from summaries of data on chemicals which have partial resemblance to the notified chemical. All studies are described below. Structural data for comparison were not provided. Under these circumstances where measured data for the chemical are not provided, the worst case scenario is adopted, unless there are scientifically valid reasons not to do so.

9.1 Acute Toxicity

Summary of the acute toxicity of Priolube 3999 and its partial analogs mixed esters of trimethylolpropane with mixed heptanoic acids and 2-ethylhexanoic acid (RB 105) (structure provided), trimethylpropane (TMP) tricaprylate/tricaprate (including summaries for TMP and caprylic/capric triglyceride), polyalcohol isostearate esters propylene glycol monoisostearate, propylene glycol diisostearate, neopentyl glycol diisostearate, pentaerythritol tetraisostearate, sorbitan monoisostearate and pentaerythritol tetraisostearate (Priolube 3987, structure provided))

Test	*Species*	*Outcome*	*Chemical type/Reference*
acute oral toxicity (A) full study	rat	LD_{50} > 2 000 mg/kg	(Priolube 3999) (Enninga, 1997)
acute oral toxicity (B) summary	rat	LD_{50} > 2 000 mg/kg	(RB 105)
acute oral toxicity (C) summary	rat	LD_{50}> 5 000 mg/kg	(TMP tricaprylate/tricaprate) (Rodford, 1996)
acute oral toxicity (D) summary	rat	LD_{50} = 2 000 mg/kg	(propylene glycol monoisostearate/ propylene glycol diisostearate/ neopentyl glycol diisostearate) (Rodford, 1996)
	rat	LD_{50} = 5 000 mg/kg	(pentaerythritol tetraisostearate) (Rodford, 1996)

acute oral toxicity (E) summary	rat	LD_{50} = 16 000 mg/kg	(sorbitan monoisostearate) (Rodford, 1996)

Test	***Species***	***Outcome***	***Chemical type/Reference***
acute dermal toxicity (A) full study	rat	LD_{50} > 2 000 mg/kg	(Priolube 3987) (Debets, 1984)
acute dermal toxicity (B) full study	rat	LD_{50} > 2 000 mg/kg	(RB 105)
acute inhalation toxicity (A) summary	rat/guinea pig	28.1 µL/L 1.97 µL/L (respirable)	(caprylic/capric triglyceride) (Rodford, 1996)
acute inhalation toxicity (B) summary	rat	2 mg/L	(TMP) (Rodford, 1996)
skin irritation (A) full study	rabbit	slight to moderate irritant	(RB 105)
skin irritation (B) full study	rabbit	non-irritant	(Priolube 3987) (Weterings, 1984)
skin irritation (C) summary	rabbit	slight irritant	(TMP tricaprylate/tricaprate) (Rodford, 1996)
skin irritation (D) summary	rabbit	moderate skin irritant	(propylene glycol monoisostearate/propy -lene glycol diisostearate/sorbitan monoisostearate) (Rodford, 1996)

	rabbit	slight irritant	(pentaerythritol tetraisostearate) (Rodford, 1996)
Test	***Species***	***Outcome***	***Chemical type\Reference***
	human	non-irritant	(pentaerythritol tetraisostearate) (Rodford, 1996)
eye irritation (A) full study	rabbit	non-irritant	(RB 105)
eye irritation (C) summary	rabbit	slight irritant	(propylene glycol monoisostearate/propylene glycol diisostearate/pentaerythritol tetraisostearate) (Rodford, 1996)
	rabbit	non-irritant	(sorbitan monoisostearate) (Rodford, 1996)
skin sensitisation (A) full study	guinea pig	non-sensitiser	(RB 105)
skin sensitisation (B) summary	guinea pig	non-sensitiser	(caprylic/capric triglyceride) (Rodford, 1996)
skin sensitisation (C) summary	human	non-sensitiser	(caprylic/capric triglyceride) (Rodford, 1996)

skin sensitisation (D)	guinea pig		(sorbitan monoisostearate)
summary	low sensitising	potential	(Rodford, 1996)

9.1.1 Oral Toxicity

9.1.1A Oral Toxicity (Priolube 3999) (Enninga, 1997)

Species/strain:	rat/Wistar
Number/sex of animals:	3/sex
Observation period:	15 days
Method of administration:	a single dose of 2 000 mg/kg administered by gavage
Test method:	OECD TG 401
Clinical observations:	no clinical signs of toxicity were observed during the observation period
Mortality:	none
Morphological findings:	no abnormalities detected
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.1B Oral Toxicity (RB 105)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	a single dose of 2 000 mg/kg administered by gavage
Test method:	OECD TG 401
	no clinical signs of toxicity were observed during the observation period
Mortality:	none
Morphological findings:	no abnormalities detected
LD_{50}:	> 2 000 mg/kg
Result:	RB 105 was of very low acute oral toxicity in rats

9.1.1C Oral Toxicity (trimethylolpropane(TMP) tricaprylate/tricaprate)(Rodford, 1996)

An published study carried out in accordance with OECD Guideline 401 showed TMP tricaprylate/tricaprate to rats to have a very low acute oral toxicity of >5 000 mg/kg) in rats.

9.1.1D Oral Toxicity (propylene glycol monoisostearate, propylene glycol diisostearate, neopentyl glycol diisostearate and pentaerythritol tetraisostearate) (Rodford, 1996)

Unpublished studies in rats based on OECD protocols showed propylene glycol monoisostearate, propylene glycol diisostearate and neopentyl glycol diisostearate not to be harmful at a dose of 2 000 mg/kg/bw. Pentaerythritol tetraisostearate was not toxic in rats at doses up to 5 000 mg/kg/bw.

9.1.1E Oral Toxicity (sorbitan monoisostearate) (Rodford, 1996)

Unpublished studies using sorbitan monoisostearate have shown it not to be harmful to rats at doses ranging from 10 000 mg/kg to 16 000 mg/kg.

9.1.2 Acute Dermal Toxicity

9.1.2A Acute Dermal Toxicity (Priolube 3987) (Debets, 1984)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	a dose 2 000 mg/kg was applied to an intact skin site and covered with occlusive dressing; after 24 hours the dressing and residual test material were removed
Clinical observations:	none
Test method:	OECD TG 402
Mortality:	none
Morphological findings:	none
LD_{50}:	> 2 000 mg/kg
Result:	the Priolube 3987 was of low dermal toxicity in rats

9.1.2B Acute Dermal Toxicity (RB 105)

Species/strain:	rat/Sprague-Dawley

Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	a dose 2 000 mg/kg was applied to an intact skin site and covered with semi-occlusive dressing; after 24 hours the dressing and residual test material were removed
Clinical observations:	none
Test method:	OECD TG 402
Mortality:	none
Morphological findings:	crust formation was noted at the treatment site of two females three to six days after dosing; well defined erythema was observed surrounding the crust formation at one treatment site
LD_{50}:	> 2 000 mg/kg
Result:	RB 105 was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

9.1.3A Inhalation Toxicity (caprylic/capric triglyceride) (Rodford, 1996)

Groups of 10 rats and 10 guinea pigs were exposed to caprylic/capric triglyceride aerosol in 40 L chamber. After exposure to a nominal concentration of 28.1 µL/L of air with a respirable fraction of 1.97 µL/L no gross or microscopic defects attributable to the test substance were observed. The acute inhalation toxicity of caprylic/capric triglyceride in rats was considered low at the tested concentration.

9.1.3B Inhalation Toxicity (TMP) (Rodford, 1996)

Rats exposed to TMP at concentrations ranging from 0.7 to 2 mg/L (the highest level obtainable) for 4 hours, showed no visible signs of toxicity. However, at autopsy the animals exhibited moderate congestion and slight changes to permeability of the vessel walls and hypertrophy of the parenchymatous organs and brain cells. The acute lethal inhalation toxicity of TMP in rats was low at the tested concentration.

9.1.4 Skin Irritation

9.1.4A Skin Irritation (RB 105)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 males

Observation period:	24, 48 and 72 hours after dose administration
Method of administration:	a dose of 0.5 g was applied to an intact skin site; the site was covered with semi-occlusive dressing; after 4 hours the dressing and the residual test material were removed
Test method:	OECD TG 404
Comment:	one animal had mean scores of 2.0 and 2.7 for erythema and oedema respectively, another animal had mean scores of 1.0 and 0.3 respectively and the other animal had scores of zero
Result:	RB 105 was slight to moderate skin irritant in rabbits

9.1.4B Skin Irritation (Priolube 3987) (Weterings, 1984)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 females
Observation period:	24, 48 and 72 hours after dose administration
Method of administration:	a dose of 0.5 mL was applied to an intact skin site; the site was covered with semi-occlusive dressing; after 4 hours the dressing and the residual test material were removed
Test method:	OECD TG 404
Comment:	one animal had very slight erythema and another very slight oedema one hour after removal of the test substance
Result:	Priolube 3987 was a slight irritant to rabbit skin

9.1.4C Skin Irritation (TMP tricaprylate/tricaprate) (Rodford, 1996)

An unpublished study, carried out in accordance with OECD Guideline 404, showed that undiluted TMP tricaprylate/tricaprate was a slight irritant to rabbit skin.

9.1.4D Skin Irritation (propylene glycol monoisostearate, propylene glycol diisostearate, pentaerythritol tetraisostearate and sorbitan monoisostearate) (Rodford, 1996)

Unpublished studies based on OECD protocols showed the above test substances were slight to moderate irritants to rabbit skin following single 4 hour applications.

Propylene glycol monoisostearate exhibited moderate irritation of the skin which persisted for 3 days; slight changes observed to the skin were reversible within 2 days.

Propylene glycol diisostearate exhibited moderate irritation which decreased after 24 hours and was completely resolved after 6 days.

Pentaerythritol tetraisostearate exhibited slight erythema and oedema in one animal, one hour after removal of the test substance. In another unpublished study it was slightly irritating to rabbit skin.

Sorbitan monoisostearate was considered to be a moderate irritant in a unpublished study conducted as described in the Code of Federal Regulations, Title 16, Section 1500.41.

An unpublished study performed with human subjects using pentaerythritol tetraisostearate described it as "essentially non-irritating" to human skin.

Based on above observations polyalcohol isostearate esters may exhibit slight to moderate irritation to rabbit skin.

9.1.5 Eye Irritation

9.1.5A Eye Irritation (RB 105)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 males
Observation period:	24, 48 and 72 hours after dose administration
Method of administration:	0.5 ml of the test substance was placed in the conjunctival sac of one eye of each rabbit whilst the contralateral eye served as the control
Test method:	OECD TG 405
Result:	RB 105 was non-irritant to the eyes of rabbits

9.1.5B Eye Irritation (TMP tricaprylate/tricaprate) (Rodford, 1996)

An unpublished study, carried out in accordance with OECD Guideline 405 showed that undiluted TMP tricaprylate/tricaprate was a very slight irritant to rabbit eye.

9.1.5C Eye Irritation (propylene glycol monoisostearate, propylene glycol diisostearate, pentaerythritol tetraisostearate and sorbitan monoisostearate) (Rodford, 1996)

Unpublished studies carried out based on OECD protocols showed propylene glycol monoisostearate and propylene glycol diisostearate to be non-irritating to rabbit eyes. Propylene glycol monoisostearate showed slight irritation after patch removal which was reversible after 48 hours in all three rabbits tested. Propylene glycol diisostearate also showed slight irritation which was reversible after 72 hours in all three rabbits.

Summaries based on an unpublished study showed pentaerythritol tetraisostearate caused transient conjunctival irritation and was considered a slight irritant in accordance with the Kay and Calandra classification.

Sorbitan monoisostearate was non-irritating to rabbit eyes in two unpublished studies carried out according to US FDA standards and Code of the Federal Regulations, Title Section 1500.42.

Based on the above observations polyalcohol isostearate esters may exhibit slight irritation to rabbit eyes.

9.1.6 Skin Sensitisation

9.1.6A Skin Sensitisation (RB 105)

Species/strain:	guinea pig/Dunkin-Hartley White Strain
Number of animals:	10 females (test group) 5 females (control group)
Induction procedure;	Day 1: test group 3 pairs of intradermal injections: - 0.1 mL of 1:1 (w/v) mixture of Freunds Complete Adjuvant (FCA) and arachis oil BP - 0.1mL of 25% (w/v) of test substance in arachis oil BP - 0.1 mL of 25% (w/v) of test substance in FCA and arachis oil BP control group 0.1 mL of 1:1 (w/v) mixture of FCA and arachis oil BP 0.1 mL of arachis oil BP 0.1 mL of FCA day 8 occluded application of undiluted test material over sites of injection
Challenge procedure:	day 22 occluded application of test material (75% v/v) in arachis oil on flanks
Test method:	OECD TG 406

Challenge outcome:

	Test animals	***Control animals***

Challenge concentration	*24 hours**	*48 hours**	*24 hours*	*48 hours*
75%	0/10**	0/10	0/5	0/5

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

Result: the RB 105 was not a skin sensitiser in guinea pigs

9.1.6B Skin Sensitisation (caprylic/capric triglyceride) (Rodford, 1996)

A 4% solution of caprylic/capric triglyceride showed no evidence of skin sensitisation potential when tested on male albino guinea pigs.

9.1.6C Skin Sensitisation (human study; caprylic/capric triglyceride) (Rodford, 1996)

One hundred and twenty eight adult male and female volunteers were given caprylic/capric triglyceride using a modification of the Draize repeated insult patch test. All subjects tested had little or no irritation. The study concluded that the chemical tested had no skin sensitisation potential.

9.1.6D Skin Sensitisation (sorbitan monoisostearate) (Rodford, 1996)

Five unpublished studies using guinea pigs showed sorbitan monoisostearate to have very low sensitisation potential.

9.2 Repeat Dose Toxicity

Test	*Species*	*Outcome*	*Reference*
subacute oral toxicity (A) full study	rat	no significant organ toxicity	(RB 105)
subacute oral toxicity (B) summary	rats	no mortality at 7 000 mg/kg/day	(TMP) (Rodford, 1996)
		up to 3000 mg/kg/day no external signs of toxicity	(TMP) (Rodford, 1996)
subacute-subchronic oral toxicity summary	rat and hamster	no harmful effects	(caprylic/capric triglyceride oils) (Rodford, 1996)
subacute inhalation toxicity	rat	3.5 ppm (20 µg/L) no signs of toxicity	(TMP) (Rodford, 1996)

		at 0.13 and 1.1 mg/L changes observed in circulatory system, inflammatory and degenerative organs	(TMP) (Rodford, 1996)
chronic oral toxicity	rat	at 20% for up to 18 months no toxic effects	(caprylic/capric triglyceride oils) (Rodford, 1996)
carcinogenicity	rat	no tumourigenic response	(caprylic/capric triglyceride oils)
	mouse	no tumourigenic response	(caprylic/capric triglyceride oils) (Rodford, 1996)
	NMU rat (mammary tumour model)	significantly lower total mammary tumours	(caprylic/capric triglyceride oils) (Rodford, 1996)

9.2.1A Subacute Oral Toxicity (RB 105)

Species/strain: rat/Sprague-Dawley

Number/sex of animals: 20/sex

Method of administration: gavage;vehicle arachis oil BP

Dose/Study duration: test substance administered daily for a total of 28 days:

control	0 mg/kg/day
low dose	150 mg/kg/day
mid dose	400 mg/kg/day
high dose	1 000 mg/kg/day

Test method: OECD TG 407

Clinical observations: no clinical signs noted in any dose group

Clinical chemistry/ Haematology no treatment related effects were detected

Urinalysis: no treatment related effects

Histopathology: no treatment related changes

Organ Weights: no treatment related effects

Necropsy: no treatment related macroscopic changes

Result: the notified chemical did not exhibit any significant organ toxicity min males or females

the no-observed effect level for the notified chemical (NOEL) for this 28-day rat study was $\geq$ 1 000 mg/kg/day

9.2.2B Subacute Oral Toxicity (TMP) (Rodford, 1996)

No mortality was observed on a gavage study done on rats using TMP at doses of 7 000 mg/kg/day for 12 days.

A five month rat feeding study using TMP at doses 1 500 or 3000 mg/kg/bw/day showed no external signs of toxicity and there were no differences in body weight gain compared to the controls.

9.2.3 Subacute – Subchronic Oral Toxicity (caprylic/capric triglyceride oils) (Rodford, 1996)

A number of oral studies done on rats and hamsters with caprylic/capric triglyceride oils ranging from 23 days to 3 months did not show any harmful effects.

9.2.4 Subacute Inhalation Toxicity (TMP) (Rodford, 1996)

In a three week study, two male and two female rats were exposed to 3.5 ppm (20 µg/L) of TMP 15 times for six hours. There were no signs of toxicity and no abnormalities were detected at necropsy at the tested dose.

In a three and a half month rat study using TMP in 2 experiments at mean concentrations of 0.13 and 1.1 mg/L, there were no external signs of toxicity, differences in food consumption, body weight gain or clinical biochemistry changes. However, the summary states there was unspecified dysfunction nervous system. Autopsy revealed changes to the circulatory system and inflammatory and degenerative changes in organs.

9.2.5 Chronic Oral Toxicity (caprylic/capric triglyceride oils) (Rodford, 1996)

Two rat feeding studies were performed with 20% caprylic/capric triglyceride oil for 47 weeks and 18 months. No toxic effects were noted. However, in both studies decreased body weight in the tested animals was observed.

9.2.6 Carcinogenicity (caprylic/capric triglyceride oils) (Rodford, 1996)

In two studies using rats and mice respectively the test substance was used as the control. It did not show a tumourigenic response. The rat study used 0.25 mL of sample per rat given sub-cutaneously with a post exposure period of 13 months. The mouse study used 0.1 mL of undiluted sample per mouse given sub-cutaneously with a post exposure period of 13 months.

9.2.7 Carcinogenicity (caprylic/capric triglyceride oil) (Rodford, 1996)

The N-nitrosomethylurea (NMU) rat mammary tumour model was used to compare the tumour-promoting effects of a high fat (HF) diet containing a 3:1 mixture of caprylic/capric triglyceride oil (MCT) and corn oil with that of HF: corn oil and low fat (LF): corn oil diets. Two days after after a single dose of NMU (50 mg/kg/body wt), the rats were given experimental diets for approximately 22 weeks. The results indicated that animals fed the MCT diet exhibited a significantly lower total mammary tumour incidence when compared to animals fed a HF: corn oil diet. Results for the LF diet were not provided.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Priolube 3999) (Enninga, 1997)

Strains:	*Salmonella typhimurium* TA 98, TA 100, TA 1535 and TA 1537 and *Escherichia coli* strain WP2*uvrA*
Concentration range:	based on a range finding study assay was performed in triplicate with or without metabolic activation at concentrations of 33, 100 333, 1 000 or 3 300 µg/plate; solvent control was dimethylsulphoxide
Test method:	OECD TG 471
Comment:	at 3 300 µg/plate the test substance exhibited slight precipitation with or without metabolic activation in all strains used; there were no significant increases in revertant colony numbers at any dose, with or without metabolic activation
Result:	the notified chemical is not considered to be mutagenic in bacteria

9.3.2 *Salmonella typhimurium* Reverse Mutation Assay (RB 105)

Strains:	*Salmonella typhimurium* TA 98, TA 100, TA 1535 and TA 1537 and *Escherichia coli* strain WP*2uvrA*
Concentration range:	the assay was performed in two independent experiments with or without metabolic activation at concentration ranges of 8 to 5 000 µg/plate (Experiment 1) and 312.5 to 5 000 Experiment 2) µg/plate
Test method:	OECD TG 471 (Experiment 2)
Comment:	there were no significant increases in revertant colony numbers at any dose level, with or without metabolic activation

Result:	the RB 105 is not considered to be mutagenic in bacteria

9.3.3 Chromosomal Aberration Assay in Human Lymphocytes (RB 105)

Cells:	human lymphocytes
Doses:	with or without metabolic activation: 1 250-5 000 µg/mL; cells with metabolic activation were treated with the test material for 4 hours and those without metabolic activation for 20 hours
Test method:	OECD TG 473
Comment:	no increases in cells with structural chromosomal aberrations were seen after treatment with the test article at the dose level tested, in the presence or absence of metabolic activation
Result:	the test material was not considered to be clastogenic under the conditions of this chromosomal aberration test

9.4 Reproductive Toxicity (caprylic/capric triglyceride oils) (Rodford, 1996)

Two 2-generation rat studies with 20% test material in the diet showed normal reproduction, as indicated by litter size and number. However, in both studies, the lactation performance of the rats on the test diets was poor, resulting in slower weight gain and higher mortality of the offspring.

9.5 Phototoxicity and Photoallergy

9.5.1 Phototoxicity and Photoallergy (caprylic/capric triglyceride oil) (Rodford, 1996)

An unpublished study carried out on 17 volunteers using the test substance showed no phototoxic or photosensitising effects.

9.5.2 Phytotoxicity and Photoallergy (propylene glycol monoisostearate and propylene glycol diisostearate) (Rodford, 1996)

Unpublished studies have indicated that both propylene glycol monoisostearate and propylene glycol diisostearate are devoid of phototoxic effects in the Albino guinea pig.

9.6 Comedogenicity (TMP tricaprylate/tricaprate) (Rodford, 1996)

A study carried out to assess the comedogenic potential of the test material by repeated application to the external ear canal of a New Zealand White rabbit did not show any evidence of comedogenicity. The positive control isopropyl myristate produced an increase in follicular keratosis. However this type of study, used to assess the safety of a compound as an ear canal lubricant, is not routinely provided for assessment.

9.7 Overall Assessment of Toxicological Data

The notified chemical exhibited very low acute oral toxicity in rats (LD_{50} > 2 000 mg/kg). Similar chemicals propylene glycol monoisostearate, propylene glycol diisostearate and neopentyl glycol diisostearate exhibited similar toxicity (LD_{50} = 2 000 mg/kg) in rats. Similar chemicals TMP tricaprylate/tricaprate, pentaerythritol tetraisostearate and sorbitan monoisotearate exhibited very low acute oral toxicity ($LD_{50} \geq$ 5 000 mg/kg) in rats. The analogue RB 105 was also of very low acute oral toxicity.

Analogues Priolube 3987 and RB 105 exhibited low acute dermal toxicity (LD_{50} > 2 000 mg/kg) in rats.

The analogues caprylic/capric triglyceride and TMP at air borne exposures of 28.1 µL/L and up to 2 mg/L did not show any signs of acute inhalation toxicity in rats.

The analogues TMP tricaprylate/tricaprate and pentaerythritol tetraisostearate exhibited slight irritation and RB 105 exhibited slight to moderate skin irritation to the skin of rabbit. The analogues propylene glycol monoisostearate, propylene glycol diisostearate and sorbitan monoisostearate exhibited moderate irritation to the skin of rabbits. The analogues Priolube 3987 and RB 105 were non-irritant to rabbit skin. Analogue pentaerythritol tetraisostearate was found to be a non-irritant to human skin.

Analogues TMP tricaprylate/tricaprate, propylene glycol monoisostearate, propylene glycol diisostearate and pentaerythritol tetraisostearate exhibited slight irritation to the rabbit eye. Others, RB 105 and sorbitan monoisostearate were non irritant to the rabbit eye.

The analogue sorbitan monoisostearate demonstrated low sensitising potential to the skin of guinea pigs, while analogues RB 105 and caprylic/capric triglyceride were found to be non-sensitisers to the skin of guinea pigs. The latter when tested on human skin was a non-sensitiser.

In a 28-day repeat oral dose study in rats, the analogue RB 105 did not exhibit any significant organ toxicity. Based on the absence of findings at the high dose level, the NOEL was established at $\geq$ 1 000 mg/kg/day. Other repeated dose oral toxicity studies showed the following responses:

- caprylic/capric triglyceride oils in studies of duration ranging from 23 days to 3 months did not exhibit toxicity in rats;
- TMP at a dosage of 7 000 mg/kg/day for 12 days showed no mortality in rats;
- caprylic/capric triglyceride oils at 15% concentration given to Syrian hamsters for 28-days showed no adverse effects;
- TMP at doses of 1 500 or 3 000 mg/kg/day given to rats for five months showed no signs of external toxicity;
- Two rat repeated dose oral toxicity studies using caprylic/capric triglyceride oils at 20% for 47 weeks and 18 months exhibited no toxicity;
- Two rodent carcinogenicity studies using TMP tricaprylate/tricaprate were negative.

Repeated dose inhalation toxicity studies done with:

- TMP on rats at an exposure concentration of 3.5 ppm of TMP 15 times per day for three weeks exhibited no toxicity or any other abnormalities in rats;
- TMP on Albino rats at mean exposure concentrations of 0.13 and 1.1 mg/L per day for three an a half months exhibited abnormalities in the nervous system, changes in the blood circulatory system and inflamed and degenerated organs.

An HF diet containing a mixture of caprylic/capric triglyceride in corn oil showed a significantly lower mammary tumour incidence than the HF diet alone, in the NMU rat mammary tumour model.

The notified chemical and its analogue RB 105 were found not to be mutagenic *in vitro* in a bacterial reverse mutation assay. RB 105 was not genotoxic in a chromosomal aberration assay in human lymphocytes. No *in vivo* tests were performed.

A 2-generation rat reproductive toxicity study using 20% caprylic/capric triglyceride oil showed normal litter size and number, but with poor lactation performance, slower weight gain and higher mortality of the offspring in the treated groups.

Unpublished studies done on albino guinea pigs using the analogues propylene glycol monoisostearate and propylene glycol diisostearate did not exhibit phototoxic effects.

A study carried out to assess comedogenicity in New Zealand White rabbits using TMP tricaprylate/tricaprate was negative.

In summary using the notified chemical data and worst case findings from analogue studies, the notified chemical is taken as having a low hazard according to *NOHSC Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a). The notified chemical is not determined to be a hazardous substance relation to any of the toxicological end points measured. However, based on the results of the repeated dose inhalation study on Albino rats using TMP, hazard due to inhalation cannot be ruled out.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

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

Species	Test	Concentrations[a] (mg/L)	Result (mg/L)	Reference
Carp *(Cyprinus carpio)*	96 h acute	0, 100	LC_{50} >100 NOEC ≥100	(Bogers, 1997)
Water Flea (*Daphnia magna*)	48 h acute	0, 1.0, 10, 100	EC_{50} > 100 NOEC = 1.0	(Harding, 1997)
Algae[b] (*Scenedesmus subspictus*)	72 h growth	0, 0.1, 0.32, 1.0, 3.2, 10	ERC_{50} > 10 EBC_{50} > 10 NOEC = 10	(Marshall, 1995)
Bacteria (*Pseudomonas putida)*	16 h Inhibition	10 000[c]	EC_{50} > 10 000	(Mead, 1997)

[a]Nominal concentrations [b]Test conducted on analogue compound PRIOLUBE 3988 . [c]loading rate of WSF.

The fish study was conducted as a limit test. The fish were exposed to control, a solvent control (containing acetone) and the test concentration. No mortality or other effects were observed throughout the test period.

In the daphnid study, no immobilisation was observed at the two lowest test concentrations after 24 h. Cloudiness at the highest test level prevented the counting of neonates at 24 h. At the end of the test period less than 50% immobility was observed at all test concentrations.

No data for the toxicity of the notified substance to algae has been provided. However, the notifier has provided data for the analogous PRIOLUBE 3988 which is also a TMP ester of fatty acids. The notifier indicates that PRIOLUBE 3999 contains 95% of the same fatty acids as PRIOLUBE 3988. No inhibitory effects were observed throughout the algal study.

No inhibitory effects were observed throughout the bacterial study.

The ecotoxicity data for the notified chemical indicate that notified substance is not toxic to aquatic species to the limit of its water solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical is considered to be low provided that the material is used as indicated, and that disposal of spent oil takes place via the routes indicated above.

The notifier estimates that less than 0.5% waste will be generated during blending. This waste is expected to be incinerated under local regulations at licensed waste treatment plants. An additional 500 kg (0.5% of import quantity) waste may be generated during transfer of the lubricants from containers to engine sumps.

As a component of automotive lubricants, the chemical may be released in small quantities as a result of engine oil seal leaks. There is also some potential for release to the environment during lubricant change. Since motor oils are changed regularly it is expected that

approximately 80% (maximum of 80 tonnes per annum) of the new material contained in oils would be destroyed through incineration and/or oil recycling activities. If recycled, the notified material would become associated with waste sludges from the recycling plant and most likely placed into landfill or incinerated. About 20% (maximum of 20 tonnes per annum) of the material will be used and changed by automobile enthusiasts, and it is expected that much of this may be released through inappropriate disposal into landfill, stormwater drains and other routes.

Incineration of the new compound would produce water vapour and oxides of carbon. The new compound is not readily biodegradable, but when deposited into landfill is expected to become immobilised through adsorption onto soil particles, then slowly degraded through the agency of micro-biological and abiotic processes operative in these facilities, producing water, methane and oxides of carbon. Some of the new chemical may enter water courses, but here is expected to become associated with the aquatic sediments, and is unlikely to be available for assimilation by aquatic species. The new chemical is not toxic to aquatic species up to the limits of its solubility in water.

Given that the notified chemical will be used within closed systems, the hazard during end use is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical has very low acute oral toxicity (LD_{50} > 2 000 mg/kg). Selecting the worst case scenario from analogue data, the notified chemical will have low acute lethal dermal toxicity (LD_{50} > 2 000 mg/kg) and inhalation toxicity. The chemical will have at most moderate skin irritation, slight eye irritation. and a low potential for skin sensitisation. The NOEL established in an analogue 28 day oral study is 1 000 mg/kg/day. However a subchronic repeat dose inhalation study done on a different analogue (TMP) showed abnormalities in the nervous system and circulatory system as well as inflammatory and degenerative changes in the organs. Both the notified chemical and analogue RB 105 were found to be non-genotoxic. Carcinogenicity studies on analogues were negative. Reproductive analogue studies showed higher mortality of the offspring from treated groups. Analogues showed no phototoxicity or comedogenicity. Based on the data submitted the notified chemical could not be classified as a hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a).

Occupational Health and Safety

During the importation and transportation of the notified chemical, there is unlikely to be any worker exposure, except in the event of a spill. Given that the chemical may be a moderate skin irritant, worker involved in clean up operations should use skin protection.

Exposure to the notified chemical may occur during blending and transfer to packaging containers from the blending tank. There is potential for ocular and dermal contact during transfer of the notified chemical from steel drums to the blending tank. Should exposure

occur, the notified chemical is unlikely to cause acute systemic toxicity. However, it may cause moderate skin irritation and slight eye irritation. Therefore engineering controls, such as enclosed transfer and blending processes, and the use of personal protective equipment should occur to guard against topical skin and eye effects.

The notifier has not indicated the presence of any exhaust ventilation over the blending area. This should be in place, as the inhalation studies suggest that the notified chemical may cause adverse health effects when absorbed by the respiratory route.

The MSDS for the notified chemical states that workers using the chemical should avoid breathing heated vapours and that adequate ventilation should be maintained when handling the heated product.

The finished product contains the notified chemical typically at 5% to 20% but this may be 80% in some products. Workers using the final products would be advised to limit contamination and wear eye and hand protection.

Public Exposure
Dermal and possibly ocular exposure are likely to occur when changing or replenishing automotive oil. Consequently public exposure is likely to be occasional but widespread. Although the notified chemical will generally comprise 5 to 20% of motor oils, it is likely to be of minor risk, based on its low toxicity and intermittent use. Minimal public exposure is expected from its transport, reformulation, industrial use and disposal.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

- Safety glasses should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Stndards New Zealand, 1992););
- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987);
- Impermeable gloves or mittens should conform to ASNZS 2161.2 (Standards Australia/ Standards New Zealand, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994c);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

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

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

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

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Attachment 1

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

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

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

CORNEA

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

CONJUNCTIVAE

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

IRIS

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