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May 1999

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Priolube 3977

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Priolube 3977

1. APPLICANT

Unichema International of 14 Woodruff St PORT MELBOURNE VIC 3207 has submitted a standard notification statement in support of their application for an assessment certificate for Priolube 3977 and has not applied for any information relating to Priolube 3977 to be exempt from publication in the Full Public and Summary Reports.

2. IDENTITY OF THE CHEMICAL

Chemical Name: 2-octyldodecyl isooctadecanoate

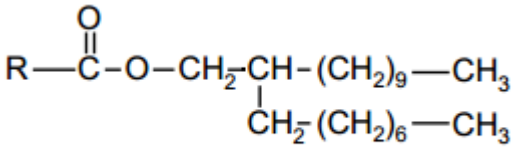
Chemical Abstracts Service (CAS) Registry No.: 93803-87-3

Other Names: 2-octyldodecyl isostearate

Trade Name: Priolube 3977

Molecular Formula: $C_{38}H_{76}O_2$

Structural Formula:



R = $C_{17}H_{35}$

the notified chemical is a conventional ester formed by the condensation of 2-octyldodecanol and isostearic acid, which is a complex mixture of branched and linear fatty acids for which the following GLC analysis of fatty acids is typical; therefore the notified chemical is a UVCB substance (a chemical of unknown or variable composition, a complex product of a

chemical reaction or a biological material, other than a whole animal or a whole plant):

Name	*% Weight*
≤ C_{14} linear chain	1.8
C_{16} branched chain	7.7
C_{16} linear chain	7.0
C_{18} branched chain	67.6
C_{18} linear chain	2.0
$C_{18:1}$ branched chain	2.3
C_{20} branched chain	8.8
C_{20} linear chain	0.2
C_{22} branched chain	1.5
C_{22} linear chain	0.2
> C_{22} chains	0.7
C_{18} lactone	0.2

Molecular Weight: approximately 564

Spectral Data: infrared (IR), ultraviolet/visible (UV/Vis) and ^{1}H-nuclear magnetic resonance (NMR) spectra were provided

Method of Detection and Determination: IR, UV/Vis and NMR spectroscopy; a gas chromatographic method was developed

3. PHYSICAL AND CHEMICAL PROPERTIES

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

Freezing Point: -42°C

Boiling Point: > 200°C

Specific Gravity: 0.86

Vapour Pressure: 0.00011 kPa at 20°C

Water Solubility: < 0.1 mg/L at 19 ±1°C (see notes below)

Partition Co-efficient (n-octanol/water):	log P_{ow} > 7
Hydrolysis as a Function of pH:	not measured – see notes below
Adsorption/Desorption:	not measured – see notes below
Dissociation Constant:	not measured – see notes below
Particle Size:	not applicable (liquid)
Flash Point:	approximately 233°C (closed cup)
Flammability:	combustible liquid
Autoignition Temperature:	365°C
Explosive Properties:	not explosive
Reactivity/Stability:	stable under normal conditions

Comments on Physico-Chemical Properties

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

The water solubility was determined (in duplicate) by vigorously stirring an excess of the new chemical with a known volume of water for 4 days. The aqueous layer was removed from the excess of chemical by repeated centrifugation, and dissolved Priolube 3977 was extracted with hexane and assayed by gas chromatography. Analytical data from the duplicate tests differed by a maximum of 10% which indicated the derived water solubility to be reliable.

No detailed test report was submitted on abiotic hydrolysis, but the notifier indicated in a statement that such a study could not be meaningfully undertaken due to the low water solubility. The chemical contains an ester group which is inherently susceptible to hydrolytic cleavage, but due to the low water solubility and very hydrophobic nature of the chemical (log $P_{ow} > 7$), intimate contact between the aqueous environment and the susceptible group is unlikely. Consequently hydrolysis of this group is unlikely, or would only occur at 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 at 22°C gave a value greater than 1000 g/L, while since the water solubility is less than 0.0001 g/L, the value of log P_{ow} is estimated to be ≥ 7. Because log P_{ow} is greater than 6, more refined determinations of this parameter cannot be carried out by either the HPLC or the flask shaking method.

No report on adsorption/desorption was submitted, but a statement provided by the notifier indicated that the study could not be undertaken due to low water solubility of the compound, and inadequate sensitivity of existing analytical techniques. However, log K_{oc} may be estimated from that of log P_{ow} using the relationship: $\log K_{oc} = 0.81 \times \log P_{ow} + 0.10$, which gives the estimate $\log K_{oc} > 5.77$. This relationship is appropriate for compounds of predominantly hydrophobic nature, and is a member of a class of QSAR recommended by the EEC for calculating K_{oc} for various classes of organic compounds (European Commission, 1996). The estimated value for log K_{oc} of greater than 5.77 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: > 98%

Toxic or Hazardous Impurities: none

Non-hazardous Impurities
(> 1% by weight): 1.5% 2-octyl-1-dodecanol (CAS No. 5333-42-6)

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical is to be used as a lubricant base fluid in products for use in 4-stroke petrol engines (motor oils). It will be imported in pure form and may also be imported in preformulated motor oils. Typical motor oil formulations contain base fluid(s) together with a range of additives to enhance oil effectiveness and longevity. The notified chemical will comprise 5 – 20% of motor oils with a minority of products containing up to 80%. Maximum import volume is expected to be 100 tonnes per year for the first five years with a minimum volume of 10 tonnes per year.

6. OCCUPATIONAL EXPOSURE

The notified chemical has a very low vapour pressure so skin contamination is the most likely route of occupational exposure. Inhalation exposure may occur if oil mists are generated, eg. during mixing.

Transport and Storage
The notified chemical will be imported in 190 kg steel drums and transported by rail or truck to blending facilities. Alternatively, products containing the notified chemical will be imported in 1000 L or 205 L containers. Exposure to waterside, transport or storage workers should only occur in the event of accidental spillage.

Formulation
Blending of the notified chemical will be accomplished by pumping from the drums in which it is imported to a closed mixing vessel of a capacity of 10 tonnes (maximum). The pump is flushed with base oil to ensure all chemical is transferred to the mixing vessel. Five workers are involved in shifting drums, removing bung lids and operating pumps. Each batch is mixed for a maximum of one hour and three batches will be made per year. Following blending, the finished product is automatically filled into 205 L, 5 L and 1 L cans. Spills are contained by onsite bunding and would be soaked up with diatomaceous earth. Larger spills would be contained within the bunded area and pumped into a waste oil truck for disposal. Skin contamination may occur during handling of the drums of notified chemical, and transfer to the mixing vessel, and from residues in lines etc. After blending, skin contact with the notified chemical may occur during the filling process, eg. in the event of spillage and overfilling. Oil mists are unlikely to be generated during the blending process, as the notifier stated that this process is enclosed. Personal protective equipment used during formulation is stated by the notifier to be limited to gloves.

End-use
Engine oil in cans will contain up to 80% notified chemical (for most uses, a maximum of 20%). End use of lubricants in garages for oil changes in motor vehicles can potentially lead to significant dermal exposure as use of gloves is uncommon.

7. PUBLIC EXPOSURE

It is expected that during transport, reformulation, storage, and use, exposure of the general public to the notified chemical will not occur, except in the event of an accidental spill. Public exposure to the notified chemical is expected to be occasional, but widespread as the 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 chemical has a low vapour pressure and is viscous in nature.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier indicates that the empty drums would be sent to a drum cleaning and recycling facility, where the unused chemical (estimated to be around 4-5 kg per drum, or approximately 2% of imports), would be washed out and the waste treated. It is expected that this waste would be treated in such a manner to 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. It is anticipated that spills would be small and contained and treated at a dedicated waste treatment facility operated by the reformulation company. The treated material would become associated with treatment plant sludge and placed into landfill or incinerated.

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, there are up to 500,000 engine oil changes (using the notified product) each year throughout Australia, and that on average 20 mL of lubricant - containing 5% of the notified substance - is likely to be either spilt or remain in containers after transfer operations, around 500 kg (0.5% of import quantity) of the notified material would be released annually.

It is anticipated that around 80% of oil changes take place in specialised automotive service centres, where used oil drained from crankcases could be expected to be disposed of responsibly - either to oil recycling or incineration. This accounts for around 80 tonne per annum (assuming 100 tonne annual import) of the notified material. The remaining 20% of oil transfer operations are expected to be performed by enthusiasts and some of the used oil would be either incinerated or left at transfer stations to be recycled, or deposited into landfill. However, recent survey data tracing the fate of used lubricating oil (see (Snow, 1997)) estimates that 20% of old oil removed by enthusiasts is collected for recycling, 25% is buried or tipped into landfill, 5% is disposed of into stormwater drains and the remaining 40% is disposed of in other ways including treating fence posts and killing grass and weeds.

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

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]. However, the test indicated 70% degradation after 28 days, which means the material can be classified as inherently biodegradable, and consequently if placed into landfill (for example adsorbed into sawdust after accidental spills) the material would be slowly degraded through the slow biological and abiotic processes operative in these facilities. These processes could be expected to produce methane, water and carbon dioxide.

Soils and Sediments
Leaching from a landfill 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 and nitrogen. Sludges from waste treatment plants or oil recycling facilities may also be incinerated.

Water and Bioaccumulation
The polymer has a relatively low molecular weight and high log P_{ow} allowing for transfer across cell membranes and assimilation into fatty tissue, together indicating the possibility for bioaccumulation. However, if released into water the high log P_{ow}, log K_{oc} and low water solubility indicate that the material would become associated with particulate organic matter and sediments, making high exposure of the chemical to aquatic fauna unlikely.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Priolube 3977

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	$LD_{50} > 2\,000$ mg/kg	(Kuszewski, 1996)
acute dermal toxicity	rat	$LD_{50} > 2\,000$ mg/kg	(Busschers, 1998a)
skin irritation	rabbit	slight to moderate irritant	(Busschers, 1998b)

eye irritation	rabbit	slight irritant	(Busschers, 1998c)
skin sensitisation	guinea pig	non-sensitiser	(Busschers, 1998d)

9.1.1 Oral Toxicity (Kuszewski, 1996)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	oral (gavage)
Clinical observations:	none
Mortality:	none
Morphological findings:	none
Test method:	OECD TG401
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Busschers, 1998a)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	under occlusive dressing for 24 hours
Clinical observations:	red staining on the neck of one female between days 8 and 13
Mortality:	none
Morphological findings:	none
Test method:	OECD TG402

LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of low acute dermal toxicity in rats

9.1.3 Inhalation Toxicity

No data provided. The notifier states that the notified chemical is not volatile at all. The notifier also claims that inhalation studies performed with rats and guinea pigs on caprylic/capric triglyceride, a short chain fatty acid ester, did not show any toxic inhalation effects.

9.1.4 Skin Irritation (Busschers, 1998b)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/male
Observation period:	72 hours
Method of administration:	0.5 mL under semi-occlusive dressing for 4 hours
Test method:	OECD TG404
Draize scores:	time points were 1, 24, 48 and 72 hours; all scores for oedema were zero at all time points; for erythema, all animals scored 2 at 1 hour and 1 at 24 hours after patch removal; in addition 1 animal scored 1 at 48 hours; all other scores were zero
Result:	the notified chemical was a slight to moderate skin irritant in rabbits on the basis that moderate erythema was observed 1 hour after exposure resolving to slight erythema in all rabbits at 24 hours and persisting in one animal to 48 hours

9.1.5 Eye Irritation (Busschers, 1998c)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/male
Observation period:	72 hours

Method of administration:	0.1 mL instilled into one eye of each of three rabbits
Test method:	OECD TG405
Draize scores:	time points were 1, 24, 48 and 72 hours; all animals scored 1 for conjunctival redness at 1 hour post-instillation which persisted in one animal over 24 hours; all other scores for conjunctival, iridal and corneal effects were zero
Result:	the notified chemical was a slight eye irritant in rabbits on the basis of slight conjunctival redness in all rabbits persisting over 24 hours in one rabbit

9.1.6 Skin Sensitisation (Busschers, 1998d)

Species/strain:	guinea pig/Himalayan
Number of animals:	5 females (control), 10 females (test)
Induction procedure:	3 pairs of intradermal injections (0.1 mL/site) as follows: - 1:1 (w/w) of Freund's Complete Adjuvant (FCA) and water; - undiluted notified chemical; - 1:1 (w/w) mixture of the undiluted notified chemical and FCA on day 7 the scapular area between the injection sites was treated with 10% sodium dodecyl sulphate in vaseline; on day 8 the above scapular area was treated with 0.5 mL of the notified chemical under occlusive dressing for 48 hours;
Challenge procedure:	on day 21 the flank was treated with 0.5 mL of the notified chemical under occlusive dressing for 24 hours

Challenge outcome:

	Test animals		*Control animals*	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
100%	0/10**	0/10	0/5	0/5

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

Test method: Magnusson and Kligman maximisation test, OECD TG406

Result: the notified chemical was not a skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (de Hoog, 1998)

Species/strain: rat/Wistar

Number/sex of animals: 5/sex/dose group

Method of administration: oral gavage

Dose/Study duration: 0, 50, 200 or 1 000 mg/kg/day for 28 days

Clinical observations: none related to treatment; incidental findings included alopecia, salivation, red staining of the skin, scabs and piloerection

Macroscopic findings/Organ weights: no findings related to treatment; watery fluid in the uterus of 2 females was related to a stage in the oestrus cycle; red foci in the lungs was noted amongst treated and/or control animals

Clinical chemistry/Haematology: no findings related to treatment; reductions of 4% in calcium and chloride levels in high dose males were assumed to be due to chance; minor statistically significant differences in high dose females were a decrease in neutrophilic granulocytes judged to be due to high numbers in controls; low relative numbers of lymphocytes in high dose females resulted; all values remained within historical controls

Histopathology:	no treatment-related findings; a small number of findings recorded were within the normal range of background alterations which may be seen in untreated rats of the strain and age used in the study
Test method:	OECD TG407
Result:	the notified chemical exhibited no organ toxicity at doses up to 1 000 mg/kg/day for 28 days; the NOEL was 1 000 mg/kg/day

9.3 Genotoxicity

9.3.1 Bacterial Reverse Mutation Assay (Verspeek-Rip, 1998)

Strains:	*Salmonella typhimurium* TA 1535, TA 1537, TA 98, TA 100; *Escherichia coli* WP2*uvrA*
Concentration range:	3 – 5 000 µg/plate (range-finding study with TA 100 and *E. coli* WP2*uvrA*) 10 – 1 000 µg/plate (main study)
Test method:	OECD TG471, TG472
Comments:	the notified chemical precipitated in the top agar at concentrations of 333 and 1 000 µg/plate; precipitation on the plates was observed at the start and at the end of the incubation period at the concentration of 1 000 µg/plate in all tester strains; the background lawn was not reduced at all concentrations tested and no decrease in the numbers of mutants was observed; no dose-related, two-fold increase in the number of mutants was observed in any strain in 2 independent experiments
Result:	the notified chemical was not mutagenic in bacteria in either the absence or presence of metabolic activation provided by Aroclor1254-induced Wistar rat liver S9 fraction; negative controls were within normal bounds and positive controls demonstrated the sensitivity of the assay

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Bertens, 1998a)

Species/strain:	mouse/CD-1
Number and sex of animals:	5/sex/sampling time
Doses:	500, 1 000 or 2 000 mg/kg; bone marrow sampled at 24 hours at all doses and at 48 hours for control and high dose animals
Method of administration:	intraperitoneally
Test method:	OECD TG474
Comment:	the animals treated with 500, 1 000 or 2 000 mg/kg showed no abnormalities as did the animals of the negative and positive controls; the incidence of micronucleated polychromatic erythrocytes in the control animals were between or equal to the minimum and maximum value of the historical control data range (male: 0 and 3 (mean 0.7) and female: 0 and 3 (mean 0.5); the animals of the groups treated with the notified chemical showed no decrease in the ratio of polychromatic to normochromatic erythrocytes compared to the vehicle controls, which reflects a lack of toxic effects of this compound on erythropoiesis; the animals of the positive control group (cyclophosphamide-treated) showed a decrease in the ratio of polychromatic to normochromatic erythrocytes
Result:	the notified chemical was not clastogenic *in vivo* as indicated by a similar frequency of micronucleated mouse bone marrow polychromatic erythrocytes in treated and control mice; the positive control indicated the sensitivity of the assay and the negative control gave the expected background response

9.3.3 Chromosomal Aberrations in Cultured Peripheral Human Lymphocytes (Bertens, 1998b)

Cells:	stimulated cultured human peripheral blood lymphocytes

Doses:	0, 100, 333 or 1 000 µg/mL culture medium; in the absence of microsomal enzymes (from Aroclor1254-induced Wistar rat liver S9 fraction) either a 24 hour treatment time and a 24 hour fixation time or a 48 hour treatment time and a 48 hour fixation time (1 000 µg/mL dose) was used; in the presence of S9 fraction treatment time was 3 hours and fixation time 24 or 48 hours (1 000 µg/mL dose)
Test method:	OECD TG473
Comment:	in the dose range finding test, the notified chemical precipitated in the culture medium at a concentration of 1 000 µg/mL and this was, therefore, used as the highest concentration in the main studies; no clear affect of the notified chemical on mitotic index was observed under the various treatment conditions; the number of cells with chromosomal aberrations found in the solvent control cultures were within the laboratory historical control range (min = 0, max = 5; mean = 0.9 aberrant cells per 100 metaphases in the absence of S9 and min = 0, max = 5; mean = 0.7 aberrant cells per 100 metaphases in the presence of S9)
Result:	the notified chemical was not clastogenic *in vitro* as judged by similar frequencies of chromosomal aberrations in treated and control cultures; the positive control substances demonstrated the sensitivity of the assay

9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity and low acute dermal toxicity in rats (LD_{50} > 2 000 mg/kg in both studies). It was a slight to moderate skin irritant and a slight eye irritant in rabbits, was not a skin sensitiser in guinea pigs and was not genotoxic *in vitro* or *in vivo*. No organ toxicity was observed in a 28-day oral gavage rat study in which the NOEL was established as the top dose, 1 000 mg/kg/day.

The notified chemical is not classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a) on the basis of the toxicological data supplied.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

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

Test	*Species*	*Results (Nominal)*
Acute Toxicity [OECD 203]	*Cyprinus carpio* (Carp)	LL_{50}(96h)>100 mg/L
Acute Immobilisation [OECD 202 - Part 1]	*Daphnia magna*	EL_{50}(48h)>86 mg/L
Reproduction [OECD 211]	*Daphnia magna*	No data - see notes below.
Growth Inhibition [OECD 201]	Algae *Selenastrum capricornutum*	No data - see notes below.
Respiration Inhibition [OECD 209]	Aerobic Waste Water Bacteria	No inhibition - see notes below.

The tests on carp were performed using the water accommodated fractions (WAFs) of the test material in a semi-static (renewal) system over a 96 hour period at a temperature of 20.3±0.3°C. Approximately 80% of the water was removed daily and replaced with fresh water containing two WAFs of the test material produced at nominal loadings equivalent to 10 and 100 mg/L. Each WAF was prepared by stirring the requisite quantity of test substance with purified tap water (reverse osmosis) for 23 hours. Seven fish were used at each nominal WAF loading and no mortality occurred over the 96 hr test period with either test. Accordingly the lethal loading (50% mortality) is > 100 mg/L. No aberrations in behaviour of the fish were noted over the test duration. However, it was noted that a film of the test substance formed on the surface of the water, which is a consequence of the low true solubility in water.

In conjunction with this investigation on toxicity to fish, a reference test using pentachlorophenol as test material was performed. All fish died after 24 hours exposure at a nominal concentration of 0.22 mg/L.

The conclusion from this test is that the new compound is not toxic to carp up to the limits of its solubility in water.

The acute immobilisation tests on daphnia were also performed in a static test over a 48 hour period with one WAF prepared at a nominal loading of 86 mg/L, much higher than the water solubility of the compound. The test was conducted in duplicate using 10 daphnia in each. No immobilisation was observed over the 48-hour test duration with either duplicate. The results of this test indicate that the compound is not toxic to daphnia up to the limits of its solubility. As with the fish test, a film of undissolved compound was observed on the surface of the water during these tests. This had the effect of physically trapping the animals during preliminary range finding tests at high WAF loadings.

In parallel with this study, a reference test was performed with potassium dichromate using 10 daphnia. This material produced 100% immobilisation after 48 hours exposure at a concentration of 1.0 mg/L.

Although the notifier addressed the statutory requirement for a test report on the chronic toxicity (reproduction test) to daphnia, it was not possible to conduct this test in an acceptable manner due to the low water solubility of the compound and non-availability of an analytical technique of sufficient sensitivity. However, it was noted that bio-available concentrations of the chemical in water are unlikely due to the low water solubility and high value of log P_{ow} which would tend to make the compound associate with sediments.

Inhibition of increase in algal biomass was also determined using a static test over a 72 hour test period with WAFs of the notified substance with nominal loadings of 10 and 100 mg/L. Some inhibition of growth was observed with the 100 mg/L WAF (31.2%), but this was interpreted as being due to light deprivation resulting from the turbid nature of the WAF preparation rather than to intrinsic toxicity. The turbidity was a consequence of low solubility of the test material in water, and the results of this indicate the chemical is not toxic to this species of algae up to the limits of its solubility.

Dedicated tests on the effect of the new material on the respiration of activated sludge bacteria were not conducted, but a toxicity test performed as part of the biodegradation study [OECD TG 301B - modified Sturm test] indicated that the new chemical had no inhibitory effect on the ability of aerobic bacteria in sewage sludge to degrade acetate.

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 used oil takes place via the routes indicated above.

Minor quantities of the chemical when used in automotive lubricants may be released from engine oil seal leaks, and 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% (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 then most likely be placed into landfill or incinerated. About 20% (20 tonnes per annum) of the material will be used and changed by automobile enthusiasts, however it is expected that much of this will 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, and to be 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 not 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

According to the toxicological data supplied, the notified chemical does not exhibit acute or subchronic toxicity, is not a skin sensitiser and is not genotoxic. Although the notified chemical may be a slight to moderate skin irritant and a slight eye irritant, it is not classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a).

Occupational Health and Safety
Exposure to waterside, transport or storage workers should only occur in the event of accidental spillage.

The notified chemical is likely to be contained in products within the range 5 - 80%. The products will be formulated by blending the notified chemical and other ingredients in a large mixer and filling into 1, 5 and 205 L containers. As the formulation process is largely enclosed, and the notified chemical is virtually non-volatile, exposure to workers is likely to occur only during handling of drums of the notified chemical, transfer to the mixing vessel and from spillage and contact with residues in lines etc. During these processes, skin and eye irritation may occur, particularly if the recommended personal protective equipment (PPE) is not worn. Spills are contained by onsite bunding and would be soaked up with diatomaceous earth. Larger spills would be contained within the bunded area and pumped into a waste oil truck for disposal. The notifier has not indicated that any PPE is used by workers clearing up spills. The MSDS for the pure notified chemical suggests an apron and gloves should be used for thermal protection but, as the spilt material is likely to be at ambient temperature these precautions presumably do not apply. However, the MSDS states that eye protection should be used when handling the notified chemical.

Overall, based on the enclosed process and the small number of batches the risk of adverse health effects due to the notified chemical during formulation is low.

During end-use, eg. changing motor oil at garages and service stations, substantial dermal exposure may occur. Therefore, although the concentration of notified chemical is at 80% maximum (mostly 20% maximum), the risk of skin and eye irritation during end-use is significant, particularly if PPE is not worn.

Public Health
Dermal and possibly ocular exposure are likely to occur when an oil change is undertaken, or replenishment of automotive oil occurs. Consequently public exposure is likely to be occasional but widespread. Although the notified chemical will comprise up to 80% of motor oils, the risk of adverse public health effects is likely to be low based on a low hazard and intermittent use. Minimal public exposure is expected from its transport, reformulation, industrial use, or disposal.

13. MATERIAL SAFETY DATA SHEET

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

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

14. RECOMMENDATIONS

The following safety phrases should be included on labels and MSDS: S24: avoid contact with skin and S25: avoid contact with eyes.

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

- Goggles, gloves and overalls conforming to Australian Standards should be worn during formulation. Gloves should be worn during end-use.
    - goggles should conform to AS 1336 and AS 1337, gloves should conform to AS 2161.2 and overalls should conform to AS 2919;

- Spillage of the notified chemical should be avoided. Spillage should be cleaned up promptly with absorbents or pumped directly 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.

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. Specifically, if the notified chemical is to be used in cosmetics, secondary notification under subsection 64(1) will be required.

16. REFERENCES

Bertens AMC (1998a) Micronucleus Test in Bone Marrow Cells of the Mouse with Priolube 3977, Project No. 227757, NOTOX B.V., 's Hertogenbosch, The Netherlands.

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de Hoog SCM (1998) Subacute 28-Day Oral Toxicity with Priolube 3977 by Daily Gavage in the Rat, Project No. 227317, NOTOX B.V., 's Hertogenbosch, The Netherlands.

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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