File No: NA/451

Date: May 1997

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

MCP 1604

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act), and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 am and 12.00 noon and 2.00 pm and 4.00 pm each week day except on public holidays.

For Enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 9577-9466 **FAX (61) (02) 9577-9465**

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

MCP 1604

1. APPLICANT

Hellay Laboratories of 8/9 Monterey Road DANDENONG VIC 3075 has submitted a standard notification statement with their application for an assessment certificate for MCP 1604.

2. IDENTITY OF THE CHEMICAL

MCP 1604 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore, the exact molecular weight, low molecular weight species, spectral data, exact import volume and identity of trace amounts of hazardous impurities have been exempted from publication in the Full Public and Summary Reports.

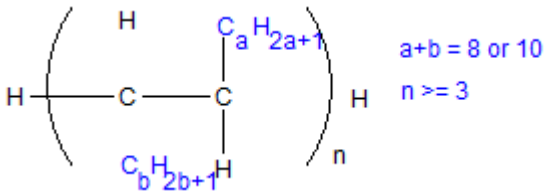
Chemical Name: 1-dodecene, polymer with 1-decene, hydrogenated

CAS Number: 151006-60-9

Other names: polyalphaolefins, PAO

Trade name: MCP 1604

Structural formula:



Molecular weight: < 1 000

Weight percentage of

ingredients:

Chemical Name	*CAS No.*	*Weight %*
1-decene	872-05-9	2-98%
1-dodecene	112-41-4	2-98%
hydrogen	1333-74-0	< 1%

Method of detection and determination: gas chromatography

Spectral data: a gas chromatogram was provided

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: bright, clear liquid

Boiling Point: not determined

Relative Density (15/4°C): 0.825

Vapour Pressure: < 13.3 Pa at 25°C

Water Solubility: negligible

Viscosity: 5.7 cSt (100°C); 29.1 cSt (40°C)

Partition Co-efficient (n-octanol/water): log P_{ow} ~ 6.8

Hydrolysis as a function of pH: not determined

Adsorption/Desorption: not determined

Dissociation Constant: not determined

Flash Point: 244°C

Comments on Physico-Chemical Properties

Experimentally obtained physical and chemical data for the notified polymer were not provided. The notifier provided estimates based upon studies performed on two very similar structured polymers, *NA/328* (*1-dodecene, polymer with 1-decene and 1-octene, hydrogenated*) and *1-decene, homopolymer, hydrogenated*. The notified polymer is expected to exhibit very similar properties to these two polymers.

The notifier claims that the water solubility will be negligible, < 0.4 mg/L. This was determined from a related polymer (NA/328: MCP 1602), which is both structurally and chemically similar, thus exhibiting similar hydrophobicity. It is accepted that the water solubility of the polymer will be < 1 ppm.

The octanol/water partition coefficient was based upon the calculated log P of MCP 1602. The notified polymer has a slightly lower number-average molecular weight (NAMW), and less trimer and tetramer content. Therefore, the notifier expects that the log P for the notified polymer would be slightly less.

Hydrolysis, adsorption/desorption and dissociation constant were not determined because of the expected low water solubility and also because they could not be measured analytically. The notifier claims that the polymer contains no functionalities that would be subject to hydrolysis, or dissociation, under the expected environmental conditions of use. This is accepted and it is noted that while the polymer cannot be measured analytically and adsorption/desorption cannot be determined, mobility through soil would be slow because of its expected strong adsorption to, or association with, soil because of its high P_{OW}.

4. PURITY OF THE CHEMICAL

Degree of purity: > 99%

Toxic or hazardous impurities: toxic impurities are present at levels below 0.01%

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

Additives/adjuvants: < 0.005%

5. USE, VOLUME AND FORMULATION

The notified chemical is intended to be used as a synthetic base stock for use in lubricating oils for consumer use (automotive oils) where it will comprise 60-80% of the finished oil. The notified chemical will also be used in industrial applications comprising 75-90% of the finished oil. The notified chemical will be imported at a rate of less than 100 tonnes per year for the first 5 years.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported as a component of a finished oil in 200 L steel drums. Exposure to transport workers is possible in the rare event of an accident.

Repackaging into 1 L containers for consumer use may involve the use of any of a number of different pump types and may include those operated by hand, air or electrical means. Automated pumps will be used for repackaging the notified

chemical from the majority of the drums. Exposure to the notified chemical is expected to be low but some drips and spills may be expected on each transfer from opening of drums and when lines are connected or disconnected.

Manual pumps will be used for repackaging if the number of drums (and/or surrounding conditions) limit the use of automated pumps.

During use of the finished oil in the industrial setting as gear and hydraulic oils, individuals may be exposed to drips and spills on addition to and removal from the closed systems. During industrial use in automotive garages, dermal and to a lesser extent eye contact may be possible during engine oil changes.

Disposal of waste oil is accomplished by a contractor at industrial sites. The oil is then either burned as fuel or disposed of by high temperature incineration. The oil is presumed to be pumped into a storage container for transport with exposure to drips and spills a possibility.

7. PUBLIC EXPOSURE

The notified chemical will be incorporated into lubricating oils for automotive and industrial uses. The automotive oil will be available to the general public. Dermal contact may be associated with persons adding or changing oil in motor vehicle oils. The notified chemical, which will be incorporated in the automotive oils at a concentration of 60-80%, is expected to be a slight dermal and a slight to moderate ocular irritant, and it is expected that the oil will possess similar properties.

The potential for minor public exposure exists during transport and disposal of the chemical/formuated oil if accidentally spilt. This is expected to be minimised by the recommended practices during storage and transportation.

8. ENVIRONMENTAL EXPOSURE

Release

The notified polymer will be imported as part of a finished product, thus there will be no manufacture or reformulation processes in Australia.

A major source of environmental release of the notified polymer is in the unlikely event of an accident during transport and/or handling of the oil product. The oil can be contained with inert materials and the mixture can be shovelled into a suitable container for disposal.

The product containing the notified polymer will be repackaged into 1L containers. This will be principally carried out by one oil company at one site. The notifier claims that if the equipment is operating properly and correct procedures are followed, no leakage or spillage during repackaging is anticipated. A variety of pumps may be used to transfer the oil, eg hand operated, air, electrical. The equipment will be cleaned by either having air blown through the lines, or flushing them with water or a

solvent (depending upon compatibility with other products). This resultant waste will be collected by a hazardous waste hauler and disposed of according to applicable regulations.

The notifier has estimated the residue of polymer remaining in the 200 L drums to be less than 0.3 kg. This equates to approximately 150 kg per year with a maximum import of 100 tonnes. The drums will be collected by a reconditioner. Washings from the cleaning process will be passed to an on-site waste water treatment plant (according to water authority regulations). The drums will be put back into circulation.

Residues in the 1L containers used by the general public are estimated at less that 0.008 kg. The containers are made of recyclable plastic and consumers are encouraged to recycle them. However, it is expected that many of these containers are likely to be disposed of to landfill.

The amount of notified polymer that may be lost to the environment during handling and use has been estimated by the notifier to be less than 70 kg per year. The notifier claims that the new synthetic oil product has a significantly longer life than mineral based oil, thus its draining interval is longer. This extended interval between oil changes results in less waste.

The industrial oils containing the notified polymer will be used in gear oils and hydraulic oils, both of which are closed systems with limited potential for environmental exposure. Hydraulic systems lose very little volume over the service life of the oil (1). Automotive oils will be supplied to automotive supply stores, automotive garages and automotive dealers. Release to the environment of the oils may occur due to engine leaks and during engine oil changes. Collected used oils will be either re-used/recycled/cleaned or burnt for their fuel value.

Fate

The notified polymer will be used in automotive and industrial oils and will share their fate. Therefore, most spent oil will be combusted, if used for fuel or recycled. A minor component will be released to the environment from spills and leaks, but this would be widely dispersed. If the notified polymer was washed off road surfaces, it would be expected to adsorb to soils or sediments adjacent the road.

Collection of waste oils is more easily accomplished from industrial and commercial users than from the small but significant quantity arising from the section of the community that changes its own (D-I-Y market) (1). The notifier has indicated that up to 20 tonnes of the polymer will be used in the oil product supplied for automotive lubricants. It is estimated from the ANZECC Report (1) that 35% of the oil used for automotive purposes will not be collected and could be disposed of in an inappropriate manner[1].

biodegradation

[1] No figures are available for how much automotive oil was collected for re-use, but an estimate of about 35% of all oil sold is not collected and possibly disposed of in an inappropriate manner. Therefore, this percentage will be specifically applied to automotive oils.

The ability of the notified polymer to biodegrade was not assessed. However, based on the biodegradability results of the similar polymers MCP 1602[2] and *1-decene, homopolymer, hydrogenated*[3], the notified polymer is not expected to be readily biodegradable. However, from the results, inherent biodegradability may be expected.

bioaccumulation

The bioaccumulation potential of the notified polymer was not determined. The notifier claims that it is not likely to bioaccumulate because the polymer is practically water insoluble, its log P_{OW} is approximately 6.8, and it is expected to exhibit some biodegradation with time. Given the literature (2), it is accepted that its low water solubility (< 0.002 mol/m^3) is likely to limit bioaccumulation.

9. EVALUATION OF TOXICOLOGICAL DATA

The notified chemical is a close analogue of MCP 1602 (NA/328). The toxicological data submitted for MCP 1602 are accepted as indicating the likely toxicity of the notified chemical and are given below. In addition toxicological data for another close analogue, 1-decene, homopolymer, hydrogenated were submitted and are also described below.

9.1 Acute Toxicity

Summary of the acute toxicity of MCP 1602

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	3
acute dermal toxicity	rabbit	LD_{50} > 2 000 mg/kg	4
skin irritation	rabbit	slight irritant	5
eye irritation	rabbit	slight to moderate irritant	6
skin sensitisation	guinea pig	non-sensitiser	7

Summary of the acute toxicity of 1-decene, homopolymer, hydrogenated

[2] MCP 1602's biodegradability was determined using the Shake Flask Method (US EPA 560/6-82-003, CG-2000, equivalent to the OECD 301B CO_2 Evolution Test (Modified Sturm Test) with an unacclimated sewage/soil inoculum. Carbon dioxide evolution was measured. MCP 1602 was tested at two concentrations of 10 and 20 mg carbon/L, and gave 26.8% and 41.0% conversion to CO_2, respectively, after 28 days. Therefore, MCP 1602 could not be classed as readily biodegradable.

[3] *1-Decene, homopolymer, hydrogenated* was determined to be not readily biodegradable. This was determined using the Shake Flask Method (US EPA 560/6-82-003, CG-2000) with an unacclimated sewage/soil inoculum. The polymer was tested at a concentration of 10.1 mg carbon/L. In 28 days, 49.5% of the carbon was converted to CO_2.

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 15 000 mg/kg	8
acute dermal toxicity	rabbit	LD_{50} > 5 000 mg/kg	9
acute inhalation toxicity	rabbit	LC_{50} > 2.5 mg/L	10
skin irritation	rabbit	slight irritant	11
eye irritation	rabbit	slight irritant	12
skin sensitisation	guinea pig	non-sensitiser	13

9.1.1 Oral Toxicity (3,8)

9.1.1.1 MCP 1602 (3)

Ten young adult Sprague-Dawley rats (five/sex) were administered a single dose of 2 000 mg/kg of MCP 1602 by gavage. The rats were observed for 14 days. No deaths occurred. There was no apparent treatment-related bodyweight change, however, this was difficult to assess without a control group for comparison. Soft stools were recorded in four animals within the first day of treatment. One male had coloured nasal discharge on day 14. Upon autopsy one male had a dilated pelvis in the kidney and one female had no food in the gastrointestinal tract and stomach. The oral LD_{50} of MCP 1602 in rats was greater than 2 000 mg/kg.

9.1.1.2 1-decene, homopolymer, hydrogenated (8)

A summary only was provided. Ten young adult Sprague-Dawley rats (five/sex) were administered a single dose of 15 000 mg/kg of the test substance by gavage. The rats were observed for 14 days. One female died on day 0. Diarrhoea was noted in all surviving animals on day 0. Oily body was noted in all surviving animals up to day 3 and in all males on day 4. The dead female exhibited red exudate for nose/mouth, red areas in intestines and dark liver and lungs. The oral LD_{50} of the test substance in rats was greater than 15 000 mg/kg.

9.1.2 Dermal Toxicity (4,9)

9.1.2.1 MCP 1602 (4)

Ten New Zealand White rabbits (five/sex) were dermally treated with 2 000 mg/kg of MCP 1602 under occlusive dressing for 24 hours. The observation period was 14 days. No deaths occurred. Bodyweights were variable. Soft stools were noted in all animals, generally one day after exposure. Slight to moderate irritation was observed on the test site of all animals on day two. In all animals dermal irritation was not present by day 13. The dermal LD_{50} of MCP 1602 in rabbits was greater than 2 000 mg/kg.

9.1.2.2 1-decene, homopolymer, hydrogenated (9)

A summary only was provided. Ten New Zealand White rabbits (sex not specified) were dermally treated with 5 000 mg/kg of the test substance under occlusive dressing for 24 hours. The observation period was 14 days. No deaths occurred. Chromorhinorrhea was observed in 1 animal on day 14 and in 1 animal on day 11. Diarrhoea was observed in 1 animal on days 12-14, in 1 animal on days 1 and 2 and in a further animal on day 2. Yellow discharge from the nose was noted in 1 animal on days 9-12. Slight skin irritation was observed in all animals on day 1. The dermal LD_{50} of the test substance in rabbits was greater than 2 000 mg/kg.

9.1.3 Inhalation Toxicity - Stock 509 (10)

Stock 509 - 1-decene, homopolymer, hydrogenated - containing 10 ppm Stock 1884 (unspecified antioxidant) was administered to 20 Sprague-Dawley rats (ten/sex) for 4 hours via aerosol. A control group received a sham exposure. Exposures were measured as 0.48 and 2.50 mg/L. Half of the animals were killed 1 day after exposure and the others observed for an additional 2 weeks before being killed. No animals died from exposure to the test substance. No effect on bodyweight was observed and there were no clinical signs. The only macroscopic abnormalities observed at necropsy were in the lung and were small, grossly visible surface lesions. Microscopic focal acute inflammation was observed at 1 day following exposure but not at 2 weeks. The inflammation appeared to be dose-related. The inhalation LC_{50} of the test substance in rats was greater than 2.50 mg/L.

9.1.4 Skin Irritation (5,11)

9.1.4.1 MCP 1602 (5)

Six New Zealand White rabbits (three/sex) received 0.5 mL of MCP 1602 on the intact skin under occlusive dressing for one and four hours. Corrosion did not occur on either the one-hour or four-hour test sites. Slight irritation was noted in all animals exposed to MCP1602 for four hours. This irritation was in the form of erythema (grade 1) and was observed at 4.5 hours for five rabbits and at hour 52 for the other animal. The mean erythema and oedema scores were 0.1 and 0.0 and the primary irritation index was 0.0. MCP 1602 was considered a slight irritant to rabbit skin.

9.1.3.2 1-decene, homopolymer, hydrogenated (11)

A summary only was provided. Six New Zealand White rabbits (three/sex) received 0.5 mL of the test substance under occluded patch (duration not specified). No oedema was observed in any animal at either 24 or 72 hours. Slight erythema was observed in 2 animals at both 24 and 72 hours. The test substance was considered a slight irritant to rabbit skin.

9.1.4 Eye Irritation (6,12)

9.1.4.1 MCP 1602 (6)

Six New Zealand White rabbits (three/sex) received 0.1 mL of MCP 1602 into the conjunctival sac of one eye. No irritation of the cornea or iris was observed. Moderate conjunctival irritation was noted in all animals after one hour, in the form of redness (grade 2-1), chemosis (grade 1) and discharge (grade 3). Slight irritation was noted in 2/6 animals after 72 hours. The Draize scores after 1, 24, 48 and 72 hours were: 10.0, 3.7, 1.3 and 0.7, respectively. The mean days 1-3 EEC scores (combined mean score for the first three evaluation periods) for conjunctival redness and swelling were 0.7 and 0.2, respectively. MCP 1602 was a slight to moderate eye irritant in rabbits.

9.1.4.2 1-decene, homopolymer, hydrogenated (12)

A summary only was provided. Six New Zealand White rabbits (mixed sex) received 0.1 mL of the test substance into the conjunctival sac of one eye. No irritation of the cornea or iris was observed. No conjunctival discharge was observed in any animal at 1 hour or 1, 2, 3, 4 or 7 days after instillation. Slight chemosis was observed in 1 animal at 1 day; slight redness in 5 animals at 1 hour and 1 day and slight redness in 1 animal at 1 hour only post-instillation. The test substance was a slight eye irritant in rabbits.

9.1.5 Skin Sensitisation (7,13)

9.1.5.1 MCP 1602 (7)

The skin sensitisation potential of MCP 1602 was studied in Dunkin-Hartley albino guinea pigs using the Buehler Test. A primary irritation study was carried out on four animals using four concentrations of MCP 1602. Guinea pigs were subjected to a six hour topical application of MCP 1602 (neat) under occlusive dressing once a week for three weeks. 2,4-dinitrochloro-benzene (DNCB) (0.05% w/v in acetone) was used as a positive control group. Two negative control groups were used. Ten to fourteen days after the completion of the induction procedure all animals were challenged with either a topical application of MCP 1602 or DNCB.

None of the MCP 1602-treated animals responded to the challenge dose. All DNCB-treated animals displayed signs of induction. MCP 1602 when applied dermally was found to be a non-sensitiser in guinea pigs.

9.1.5.2 1-decene, homopolymer, hydrogenated (13)

The skin sensitisation potential of Stock 509 was studied in Dunkin-Hartley albino guinea pigs using the Buehler Test. Neat Stock 509 was applied dermally to 10 female guinea pigs one time per week for 3 weeks. Twenty and 27 days following the third application, challenge and rechallenge doses were applied to the “induced” animals.

Induction, challenge and rechallenge were for 6 hours under occluded patches. Challenge and rechallenge were scored 24 and 48 hours after patch removal. Induction was with neat Stock 509 and challenge and rechallenge were with a 75% (w/w) concentration.

Positive control animals (DNCB-treated) gave the expected responses. For animals treated with Stock 509 the maximum response was barely perceptible erythema. At challenge 2/10 induced and control animals exhibited a response at 24 hours; at 48 hours the figures were 2/10 and 3/10, respectively. At rechallenge no response was observed. Stock 509 was found not to be a skin sensitiser in guinea pigs.

9.2 Repeated Dose Toxicity

9.2.1 MCP 1602 (14)

Sprague-Dawley rats (ten/sex/group) were treated dermally with 0, 125, 500 or 2000 mg/kg/day of neat MCP 1602 five days per week for four weeks. An additional ten rats per sex (satellite group) were treated with 0 or 2000 mg/kg/day MCP 1602 for four weeks (five days/week) and observed for a further 14 days. The application site was not covered. Elizabethan collars were fitted to minimise ingestion of the test substance. Residual test material was not wiped off. Along with the normal systemic toxicity parameters, dermal irritation and chronic deterioration of the skin were assessed.

One animal (satellite, control, female) died after blood collection. Irritation of the neck, presumably caused by the collar, was observed in a number of animals (including controls). Red nasal discharge was noted in all animals. Chromodacryorrhea was noted in nearly half of the animals. Dermal irritation of the application site did not occur.

Males treated with 2 000 mg/kg displayed decreased bodyweight gain. This difference was significant for satellite males. Increased food consumption was occasionally noted for 2 000 mg/kg females, although these appear not to be treatment-related.

The only significant difference in haematology parameters was an increase (twice the control and other treated groups) in segmented neutrophils in 2 000 mg/kg males at week five. The male satellite group did not show a significant increase in segmented neutrophils.

Satellite males which had been treated with 2 000 mg/kg MCP 1602 had significantly altered alkaline phosphatase, albumin/ globulin ratio, calcium and phosphorus levels at week five but not week seven. Triglyceride concentrations were significantly increased in satellite, 2 000 mg/kg females at both weeks five and seven.

No significant differences were noted in organ weights of control and treated animals. One high dose male (week five) had a scab in the treatment area. No other apparent treatment-related gross pathological abnormalities were noted.

After four weeks of dermal exposure to 2 000 mg/kg MCP 1602 rats displayed increased incidences of the following skin conditions: hyperplasia of the sebaceous glands for 18/20 rats, hyperplasia/ hyperkeratosis of the epidermis for 17/20 rats and dermal inflammation in 7/20 rats. After two weeks recovery no satellite-treated females displayed any dermal histomorphological changes. However, 4/10 satellite-treated males had epidermal hyperplasia / hyperkeratosis.

No target organ toxicity was identified other than the skin at the site of application.

9.2.2 1-decene, homopolymer, hydrogenated (15)

A 90-day feeding study was conducted with Fischer 344 rats administered 0, 200 or 20 000 ppm test substance in the diet (10 animals per group per sex).

Food consumption was comparable in all groups of animals. Two animals died during blood sampling at week 13 but no others died or were sacrificed before the scheduled necropsy.

No clinical signs of systemic toxicity were observed during the study. No statistical differences in the group mean body weights were observed during the study. No toxicologically significant effects on haematological parameters were observed in any dose group.

Statistically significant differences (marginal effects) on serum chemistry parameters were observed. After 5 and 13 weeks differences in glucose levels in males and sodium, phosphorus and calcium levels in females were found. After 5 weeks a slight difference in alanine transferase (ALT) in males was also observed.

No target organ toxicity was identified.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (16,17)

9.3.1.1 MCP 1602 (16)

Strains of *Salmonella typhimurium* (TA98, TA1537, TA1538, TA100 and TA1535) were cultured with 0.1-10.0 mL/plate of MCP 1602 in tetrahydrofuran. Tetrahydrofuran was the only 'preferred' solvent in which MCP 1602 was soluble. The assays were performed either in the absence or presence of rat liver S9. The rat liver microsomal fraction (S9) was prepared from male Sprague-Dawley rats that had been treated with Aroclor 1254. 2-amino-anthracene, 2-aminoacridine, N-methyl-N'-nitro-N-nitrosoguanidine and 2-nitrofluorene were used as positive controls. Positive controls were dissolved in dimethyl sulphoxide. Vehicular controls were also used.

Due to the toxicity of tetrahydrofuran, only the plate incorporation assay was performed. There were no dose-related or significant increases in the number of revertant colonies in any of the test strains used, either in the presence or absence

of metabolic activation. The positive controls behaved as expected. Under the test conditions, MCP 1602 was not mutagenic in *S. typhimurium*.

9.3.1.2 1-decene, homopolymer, hydrogenated (17)

The study was designed to rank the mutagenicity of a dimethylsulfoxide extract of Stock 509 (with 10 ppm Stock 1884 - an antioxidant) relative to other oil extracts of known mutagenicity and dermal carcinogenicity employing a modified Ames test. In this test a single strain, TA 98, is used. Additionally, an 8-fold higher concentration of hamster liver S9 fraction in the presence of a 2-fold higher concentration of NADP cofactor relative to the standard Ames test are employed.

After a 20 minute preincubation with up to 80 μL of Stock 509 treated bacteria were plated on selective medium. Positive controls gave the expected responses.

No increase in mutant numbers above background was observed. Under the test conditions Stock 509 was not mutagenic in *S. typhimurium*.

9.3.2 Chromosomal Aberrations in Chinese Hamster Ovary (CHO) Cells (18)

Chinese hamster ovary cells (CHO-WBL) were treated with MCP 1602 in tetrahydrofuran. This study was performed in three parts; preliminary toxicity range study, metaphase assay and independent metaphase assay. These experiments were performed both in the presence or absence of metabolic activation. For metabolic activation, a microsomal liver fraction (S9) was prepared from male Sprague-Dawley rats that had been treated with Aroclor 1254. Tetrahydrofuran was used as a negative control. Mitomycin C and cyclophosphamide monohydrate (CP) were dissolved in Hank's Balanced Salt Solution (HBSS) and used as positive controls for the experiments without and with metabolic activation, respectively.

In the preliminary toxicity range study doses of 0.0032, 0.0063, 0.013, 0.025, 0.05, 0.10, 0.20, and 0.40 μL/mL MCP 1602 were used. The highest dose used was limited by the solubility of the test substance in the culture medium. In both cultures containing the S9 fraction and those without it there were no signs of obvious cytotoxicity. In the S9 mixture there was no reduction in Mitotic Index (MI) relative to the negative control. Only a slight reduction (9%) in MI was noted at 0.1mL/mL without metabolic activation. At 0.40 μL/mL MCP 1602 was not cytotoxic to Chinese hamster ovary cells.

In the metaphase assay cells were harvested 16 hours after exposure to 0.05, 0.10, 0.20 and 0.40 μL/mL MCP 1602. For the S9 mixture, a slight reduction in the MI was noted relative to the negative control. There was no increase in frequency of chromosomal aberrations in MCP 1602 mixtures. The positive control (CP) resulted in 35% aberrant cells. For the mixture without S9, no reduction in MI relative to the negative control occurred. There was no increase in frequency of chromosomal aberrations in MCP 1602 mixtures. The positive control (Mitomycin C) resulted in 17% aberrant cells.

In the repeat metaphase assay cells were harvested 16 and 40 hours after exposure to 0.05, 0.10, 0.20 and 0.40 μL/mL MCP 1602. No reduction in MI compared to negative controls occurred in these assays. There was no increase in frequency of chromosomal aberrations in MCP 1602 treated cultures at both 16 and 40 hours. The positive controls behaved as expected.

Whether in the presence or absence of metabolic activation, MCP 1602 did not cause *in vitro* chromosomal aberrations in Chinese hamster ovary cells.

9.4 Developmental toxicity of Stock 509 (19)

Stock 509, 1-decene, homopolymer, hydrogenated, with 10 ppm Stock 1884 (unspecified antioxidant), was administered once daily on gestation days 0-19 via dermal application to presumed-pregnant Sprague-Dawley rats at doses of 0, 800 and 2 000 mg/kg/day. Application sites were left uncovered and ingestion was prevented by the use of Elizabethan collars.

Mild skin irritation was observed at the application site of the test substance. Maternal food consumption and body weight gain and serum chemistry were not adversely affected by Stock 509. Nor were reproductive parameters (number of implants, resorptions or viable foetuses). No evidence of teratogenicity (abnormal development) was observed during external, skeletal or visceral examinations of foetuses. No effects on mean foetal body weights and crown-rump distances were observed.

9.5 *In Vivo* Percutaneous Absorption of Stock 509 in Rats (20)

Absorption and elimination of radiolabelled (^{3}H) Stock 509 was measured in Sprague-Dawley rats following dermal administration at 2 000 mg/kg (8 mg/cm^2 skin surface).

The topical dose was administered to the clipped dorsal surface of the animals and covered with a non-occlusive protective cell. After 24 hours the surface was wiped clean. Urine and faeces were collected at 24, 48, 72 and 96 hours post-treatment.

The rate of absorption averaged approximately 60 μg/cm^2/hr over 24 hours which was judged to be moderate. Elimination of the test substance was mainly via the faecal route (80%) and about 50% of the absorbed dose (18% of the applied dose) was eliminated in 96 hours.

9.6 Overall Assessment of Toxicological Data

The oral and dermal acute toxicities of MCP 1602 and 1-decene, homopolymer, hydrogenated were low in rats and rabbits, respectively. An acute inhalation toxicity study was not presented for MCP 1602 but the LC_{50} for 1-decene, homopolymer, hydrogenated as an aerosol was greater than 2.5 mg/L which suggests that inhalation toxicity may also be low. As the notified substance (an oil) is non-volatile

and has a high boiling point it is not expected to be inhaled. Both analogues were slight skin irritants in rabbits. Ocular exposure to MCP 1602 caused slight to moderate irritation in rabbits; exposure to 1-decene, homopolymer, hydrogenated caused slight irritation. Dermal exposure to either analogue did not result in skin sensitisation in guinea pigs.

Rats exposed dermally to repeated doses of 2 000 mg/kgday MCP 1602 had increased incidences of hyperplasia of the sebaceous glands, hyperplasia/ hyperkeratosis of the epidermis and dermal inflammation. In general, these symptoms subsided after two weeks. Males from this dose group had decreased bodyweight gain and altered serum chemistry parameters.

Rats exposed at up to 20 000 ppm in a 90-day feeding study to 1-decene, homopolymer, hydrogenated did not exhibit any clinical signs of systemic toxicity. Marginal effects on clinical chemistry parameters (glucose and ALT in males; sodium, phosphorus and calcium in females) were observed.

The above studies did not identify any target organ toxicity other than for MCP 1602 at the site of application.

MCP 1602 and 1-decene, homopolymer, hydrogenated did not induce gene mutation in *Salmonella typhimurium*. There was no increased frequency of chromosomal aberrations *in vitro* in Chinese hamster ovary cells exposed to MCP1602. Based on the studies presented neither analogue is genotoxic.

1-Decene, homopolymer, hydrogenated was shown to be moderately absorbed through the skin in rats and slowly eliminated. The rate of absorption was unexpected for a compound with a relatively high molecular weight.

On the basis of toxicological studies with close analogues the notified chemical would not be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (21) in relation to the toxicological data provided.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicity tests were supplied for the notified polymer. However, the notifier does not expect any adverse effects to fish, algae or water flea based on the testing of two similar polymers, NA/328 - MCP 1602 and 1-decene, homopolymer, hydrogenated.

Environmental Effects of MCP 1602

Ecotoxicity studies were conducted using MCP 1602 according to OECD guidelines (see table below). Due to the low water solubility of MCP 1602, test solutions were prepared to either give the water accommodated fraction, or kept in suspension through an oil-water dispersion generation system. In the former, used for water flea and algae, the oil and water are mixed well prior to testing, allowed to settle, and then the water phase used in subsequent testing. In the latter, fish were added to

tanks which were continually stirred through the test - dosing with MCP 1602 was done within one hour of addition of the fish to the test tank.

Ecotoxicity test results of MCP 1602

Test	***Species***	***Result (nominal concentrations[a], w/v, mg/L)***
Acute Toxicity 96 hr acute, static	Rainbow Trout (*Oncorhynchus mykiss*)	LC_{50} > 5010[b]
Acute Immobilisation 48 hr acute, static	Water Flea (*Daphnia magna*)	EC_{50} > 5220[c,d]
Reproduction 3 brood, chronic static-renewal	Water Flea (*Daphnia magna*)	$EC_{50\ (survival)}$ & $IC_{50\ (reproduction)}$ > 5400[c,e]
Growth Inhibition 72 hr	Algae (*Scenedesmus subspicatus*)	EC_{50} > 5220[c,d]

[a] All test solutions were analysed and were below the limit of quantitation (LOQ)[2]; [b] Test was conducted in an oil-water dispersion generation system (see text for details), LOQ = 87 mg/L, test solutions were cloudy; [c] Test was conducted with water accommodated fraction - see text for details; [d] LOQ = 2 mg/L; [e] LOQ = 1.1 mg/L.

Test solutions were analysed and no MCP 1602 could be measured[4]. The results indicate that MCP 1602 would be considered non-toxic to the organisms tested, up to the level of its solubility.

Environmental Effects of 1-decene, homopolymer, hydrogenated

The results (see table below) indicate that the polymer would be considered non-toxic to the organisms tested, up to the level of its solubility.

[4] One exception was at the start of the fish test that either indicated that the test solution had not reached equilibrium, as the test laboratory suggested, or that good mixing had not occurred. It is suspected that the mixing was poor, as the polymer was not measured in any of the test concentrations at the end of the test either.

Ecotoxicity test results of *1-decene, homopolymer, hydrogenated*

Test	*Species*	*Result (nominal concentrations, w/v, mg/L)*
Acute Toxicity 96 hr, static	Sheepshead Minnow (*Cyprinodon variegatus*)	LC_{50} > 10 000[a,b]
Acute Toxicity 96 hr, static	Bluegill Sunfish (*Lepomis macrochirus*)	LC_{50} = 4121[a,c]
Acute Immobilisation 48 hr, static	Water Flea (*Daphnia magna*)	EC_{50} > 100% WSF[d,e,f,g]
Acute Toxicity 96 hr, semi-static agitation	Brown Shrimp (*Crangon crangon*)	LC_{50} > 1000[h]
Growth Inhibition 96 hr, static	Algae (*Selenastrum capricornutum*)	EC_{50} > 1320[i]

[a] Test was conducted in an oil-water dispersion generation system (see text for details); [b] Testing of polymer concentrations 500, 1 000, 5 000 & 10 000 ppm; [c] Testing of polymer concentrations 330, 1 000, 3 300 & 10 000 ppm. Fish deaths were recorded at all concentrations after the first 24 hrs. [d] Test was conducted with water soluble fraction (see text for details); [e] Daphnia were exposed to 18, 32, 56, 72 & 97.5% WSF; [f] An EC_{50} could not be calculated using any statistical method as no daphnid immobilisation was observed; [g] Daphnids became physically entrapped in the surface oil slick during the range-finding study where the polymer was directly added to the system. Some physical entrapment and subsequent immobilisation would be expected to occur following oil exposure; [h] Test was conducted using an agitation system (see text for details) at polymer concentrations of 180, 320, 560 and 1 000 ppm; [i] Test was conducted using a direct oil approach (at polymer concentrations of 82.5, 165, 330, 660 & 1 320 ppm) since oil can affect algal growth directly via water-soluble components, or indirectly via reduced light intensity, or via gas exchange from a surface oil slick.

Due to the low water solubility of the polymer, test solutions were prepared in a variety of ways:

- the polymer was kept in suspension (small droplets throughout the water column) through an oil-water dispersion generation system (fish were added to tanks which were continually stirred through the test - dosing with the polymer was done within one hour of addition of the fish to the test tank);
- to give the water soluble (accommodated) fraction - the oil and water (ratio 1:9) are mixed well prior to testing, allowed to settle, and then the water phase used in subsequent testing;
- the polymer was mixed by an agitation system (to disperse the test material throughout the test solution); or
- direct addition of the polymer to simulate environmental exposure to algae.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified polymer will be used as a base for automotive and industrial oil blends. The main exposure will be from inappropriate disposal of oil. A worst case scenario

would be if all the uncollected oil was dumped into a sewer in some country centre. This would give a concentration of about 3.8 mg/L per day[5]. For a major city, the amount would only be about 38.4 µg/L per day. The predicted environmental concentrations are several orders of magnitude lower than the worst observed environmental concentration of LC_{50} > 1 000 mg/L for brown shrimp exposed to *1-decene, homopolymer, hydrogenated*. (Ecotoxicity tests showed that the polymer is expected to be non-toxic to aquatic organisms up to the limit of its solubility.)

However, with its use Australia wide (*ie* not concentrated in one town or city), and with good industrial and public practice, aquatic exposure to the polymer is expected to be significantly less and at concentrations well below these levels.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Based on the toxicological data for the close analogues , MCP 1602 (NA/328) and 1-decene, homopolymer, hydrogenated, the notified chemical is not expected to exhibit acute or chronic toxicity, is not likely to be a skin sensitiser and is not likely to be genotoxic. However, it is likely to be a slight skin irritant and a slight to moderate eye irritant.

Exposure of transport and storehouse workers to the notified chemical is only likely to occur in the rare event of an accident.

Exposure of workers involved in repackaging the finished oil containing the notified chemical into 1 L containers is expected to be low. Repackaging will involve mainly automated equipment so that exposure is only likely when connecting and disconnecting lines to 200 L drums. The notifier states that the likelihood of exposure is slightly greater when manually operated pumps are used but is still likely to be low. In this case the volumes are likely to be low as the oil will be sent to customers as samples.

Use of the oil in the industrial setting as gear and hydraulic oil involves manual addition to and removal from various systems. Exposure to drips and spills is possible. It is expected there will be a similar likelihood of exposure to used oil when it is pumped into and removed from tanks for disposal by incineration.

The main occupational health risk to workers involved in repackaging the imported oil containing the notified chemical and in the use as a gear and hydraulic oil is likely to be slight skin irritation. This can be minimised by the use of protective gloves and clothing as outlined below. Moderate eye irritation is a potential health risk but ocular exposure is likely to be rare. The health risk to other workers handling containers of the chemical is likely to be minimal. In the case of workers involved in disposal of used oil, the risk of adverse health effects from oil contaminants is likely

[5] Given 35% of the oil is not collected, then of the 20 000 kg of the notified polymer in automotive oil for home use, 7 000 kg would not be collected (*ie* 35% x 20 000 kg). This would be 19.2 kg/day (*ie* 7600 kg/365 days). The dilution at a rural town could reasonably be expected to be about 5 ML, while for a major city, say Melbourne, it would be 500 ML. This would give final concentrations of the oil of 3.8 mg/L per day and 38.4 µg/L per day, respectively.

to be greater than that due to the notified chemical.

The most likely health risk to members of the public is also expected to be skin and eye irritation during charging and draining of automotive engines which can be minimised by wearing hand and eye protection and practising good personal hygiene. A similar risk is expected for workers in automotive garages performing the same tasks.

13. RECOMMENDATIONS

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

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (22) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (23);
- Industrial clothing should conform to the specifications detailed in AS 2919 (24);
- Impermeable gloves or mittens should conform to AS 2161 (25);
- All occupational footwear should conform to AS/NZS 2210 (26);
- 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 material safety data sheet (MSDS) should be easily accessible to employees.

14. 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* (27).

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. Of concern

from the environmental perspective would be if the method of use changes in such a way as to greatly increase environmental exposure to the notified chemical, or if additional information becomes available on adverse environmental effects of the chemical. No other specific conditions are prescribed.

16. REFERENCES

1. Australian and New Zealand Environment Council 1991, *Used lubricating oil: Generation, recovery and reuse in Australia*, prepared by Technisearch Ltd for the Waste and Resources Committee (WRAC).

2. Connel D W 1989, "General Characteristics of organic compounds which exhibit bioaccumulation", Chapter 3, in Connel D W (ed) *Bioaccumulation of xenobiotic compounds*, CRC Press, Boca Raton, USA. p. 56.

3. Rodriguez S C *et al.* 1995, *Acute oral toxicity of MCP 1602 in the Sprague-Dawley rat*, Study No. 66105, Stonybrook Laboratories Inc., Princeton, NJ, USA.

4. Rodriguez S C *et al.* 1995, *Acute dermal toxicity of MCP 1602 in the New Zealand White rabbit*, Study No. 66106, Stonybrook Laboratories Inc., Princeton, NJ, USA.

5. Rodriguez S C *et al.* 1994, *Acute dermal irritation/corrosion of MCP 1602 in the New Zealand White rabbit*, Study No. 66108, Stonybrook Laboratories Inc., Princeton, NJ, USA.

6. Rodriguez S C *et al.* 1994, *Acute ocular irritation of MCP 1602 in the New Zealand White rabbit*, Study No. 66107, Stonybrook Laboratories Inc., Princeton, NJ, USA.

7. McClurg A L, Sheldon D L and Bailey P T 1995, *Seven week epicutaneous delayed contact hypersensitivity study in guinea pigs (Buehler Sensitisation Test) of MCP-1602 (CRU#94578)*, Study No. 66111, Stonybrook Laboratories Inc., Princeton, NJ, USA.

8. Moreno O M 1978, *Report on single dose oral toxicity in rats*, Project No. MB 78-2593, MB Research Laboratories Inc, Spinnerstown, PA, USA.

9. Moreno O M 1978, *Acute dermal toxicity in rabbits*, Project No. MB 78-2593, MB Research Laboratories Inc, Spinnerstown, PA, USA.

10. Dalbey W E, Naro P A, Mackerer C R and Mehlman M A 1988, *Final report on acute inhalation toxicity of Mobil Stock 509 with 10 ppm Stock 1884*, Study No. 60061, Mobil Environmental Health Science Laboratory, Princeton, NJ, USA.

11. Anon 1978, *M455-78 - Primary dermal irritation*, Study No. 7862, data on file, Mobil Chemical Company, USA.

12. Anon 1978, *M454-78 - Ocular irritation*, Study No. 7862, data on file, Mobil Chemical Company, USA.

13. Bailey P T 1986, *Delayed contact hypersensitivity study in guinea pigs (Buehler Sensitisation Test) of Stock 509*, Study No. 50931, Mobil Environmental Health Science Laboratory, Princeton, NJ, USA.

14. Feuston M H, Schreiner C A and Mackerer C R 1995, *Four-week systemic toxicity study of MCP-1602 administered dermally to rats*, Study No. 66109, Stonybrook Laboratories Inc., Princeton, NJ, USA.

15. Feuston M H, Schreiner C A and Mackerer C R 1994, *90-day oral feeding study in Fischer 344 Rats with SHF-61 (hydrogenated polyalpha decene) in the diet*, Study No. 65518 B, Stonybrook Laboratories Inc., Princeton, NJ, USA.

16. Reddy M V, Blackburn G R, Schreiner C A and Mackerer C K 1995, *An Ames Salmonella/mammalian microsome mutagenesis assay with MCP-1602*, Study No. 66110, Stonybrook Laboratories Inc., Princeton, NJ, USA.

17. Deitch R A *et al.* 1987, *A modified Ames pre-incubation mutagenesis assay for determination of specific mutagenicity of the DMSO extract of Stock 509 with 10 ppm Stock 1884*, Study No. 62218, Mobil Environmental Health Science Laboratory, Princeton, NJ, USA.

18. Angelosanto F A, Blackburn G R, Schreiner C A and Mackerer C K 1995, *Assay for induction of chromosomal aberrations in cultured chinese hamster ovary (CHO) cells by MCP-1602*, Study No. 66132, Stonybrook Laboratories Inc., Princeton, NJ, USA.

19. Feuston M H, Naro P A, Mackerer C R and Mehlman M A 1988, *Developmental toxicity screen in rats exposed dermally to Stock 509 with 10 ppm Stock 1884*, Study No. 60062, Mobil Environmental Health Science Laboratory, Princeton, NJ, USA.

20. Yang J J *et al.* 1992, *In vivo percutaneous absorption of unadditized SHF-61 in female Sprague-Dawley rats*, Study No. 64732, Mobil Environmental Health Science Laboratory, Princeton, NJ, USA.

21. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australian Government Publishing Service, Canberra.

22. Standards Australia, 1994, *Australian Standard 1336-1994, Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney.

23. Standards Australia, Standards New Zealand 1992, *Australian/ New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards

Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

24. Standards Australia, 1987, *Australian Standard 2919 - 1987 Industrial Clothing,* Standards Association of Australia Publ., Sydney.

25. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves*), Standards Association of Australia Publ., Sydney.

26. Standards Australia, Standards New Zealand 1994, *Australian/ New Zealand Standard 2210 - 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications,* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

27. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*, AGPS, Canberra.

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