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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

MCP 1440

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

MCP 1440

1. APPLICANT

Hellay Laboratories Pty Ltd of 8/9 Monterey Road DANDENONG VIC 3075 has submitted a standard notification statement in support of their application for an assessment certificate for the new chemical MCP 1440.

2. IDENTITY OF THE CHEMICAL

MCP 1440 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular formula, structural formula and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Trade name:	MCP 1440
Molecular weight:	> 490
Method of detection and determination:	the chemical can be determined by gas chromatography/mass spectrum (GC/MS) and high performance liquid chromatography (HPLC)

3. PHYSICAL AND CHEMICAL PROPERTIES

The following physico-chemical data were provided for the notified chemical (purity > 98.9%).

Appearance at 20°C and 101.3 kPa:	light yellow liquid
Odour:	mild (not defined)
Boiling point:	349°C (with formation of a white waxy solid)
Density:	950 kg/m^3
Vapour pressure:	4.1 x 10^{-4} Pa at 25°C
Water solubility:	0.026 - 0.68 µg/L (calculated from octanol-water partition coefficient)

Partition co-efficient (n-octanol/water): log P_{ow} = 9.5-15 (calculated, OECD TG 117 - HPLC method)

Hydrolysis as a function of pH: not available (see comments below)

Adsorption/Desorption: not performed (see comments below)

Dissociation constant: not performed (see comments below)

Flash point: 214°C at 101.6 kPa

Flammability limits: not flammable

Autoignition temperature: 379°C

Explosive properties: does not exhibit explosive properties

Reactivity/Stability: may react with strong oxidisers

Comments on physico-chemical properties

The following comments were provided by the notifier. Hydrolysis data could not be generated because the low water solubility was beyond the limit of detection. Adsorption and dissociation could not be determined and the water solubility and partition coefficient could only be calculated (not measured analytically) due to the chemical's highly hydrophobic nature. These comments were acceptable.

The low water solubility and high partition coefficient of the chemical indicate it is likely to adsorb strongly to soil/sediment and organic matter. The compound does not contain ionizable groups.

4. PURITY OF THE CHEMICAL

Degree of purity: > 98.9%

Toxic or hazardous impurities: none

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

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as the base stock in synthetic air compressor lubricants, specifically reciprocating compressors. The ester imparts antiwear and extreme pressure properties to the finished lubricant. All of the chemical will be used in air compressor lubricating oils. The notifier states that the finished oil, containing the new chemical, will only be used in these contained systems.

The volume of chemical to be imported for the first five years will be 72.5 tonne per year. The chemical will enter Australia as a component (50 - 90%) of the finished lubricating oil which will be shipped and stored in sealed drums and pails.

6. OCCUPATIONAL EXPOSURE

Finished lubricating oil containing 50-90% of the notified chemical will be imported into Australia in sealed drums and transported to the customers sites (number not provided). At the customer sites, approximately 100 compressor mechanics and fitters will add the imported product to the air compressors and drain the used lubricant. Servicing of each compressor will be conducted every 8000 hours.

The applicant has indicated that the majority of customers will store the finished oil containing the chemical in the sealed drums for direct transfer into the compressor sumps. The customers are expected to use a variety of pumps and or faucets to transfer the oil. Pumps will be inserted directly into the bung opening in the drum. The extent of exposure during transfer operations will depend on the type of pump used. Hand operated pumps, with or without a closable return actuated spring, are claimed to be of the type which return drippage to the drum. Air or electrically operated pumps may also be used.

An alternative method of transfer will be using faucets. This method is not expected to be used often as it requires the drums to be lifted so as to allow the contents to pour out. If faucets are used, they are expected to be equipped with safety mechanisms to prevent accidental or unauthorised opening. Lifting of the drums will be conducted mechanically using a lift truck, crane or chain block. Exposure should therefore be greatest during attachment and removal of the faucets.

Some customers will transfer the imported material into smaller containers to be later emptied directly into the compressors. Transfer methods will be the same as those described above. The types of containers expected to be used will be oil cans for small quantities and safety cans for larger volumes. Exposure during transfer from containers to the compressors will depend on the type used. Both types are expected to include features which minimise the potential for spillage. Oil cans of the positive delivery type are fitted with a trigger operated pump. Safety cans are fitted with self-closing spouts and fill covers. The potential for exposure may be greater if other types of containers are used.

Once the chemical is in the air compressors, worker exposure will be unlikely as the compressors are contained systems with the only opening being a high pressure air outlet valve.

Used oil will be collected, purified and returned to the sump tank using automated mechanisms. Waste oil will be transferred to storage drums for disposal. Workers may be exposed to used oil during transfer operations.

7. PUBLIC EXPOSURE

The notified chemical will be used in contained systems in industrial sites. The used oil will be disposed by registered contractors and will be incinerated or used as fuel oil. Public exposure to the notified chemical is expected to be negligible.

In the case of accidental spillage during transport, the public may be exposed to the notified chemical. However, the exposure will be minimal if the spills are contained and cleaned up following the recommended practices outlined in the Material Safety Data Sheet (MSDS).

8. ENVIRONMENTAL EXPOSURE

Release

The substance will be imported into Australia in sealed drums as a component in a finished oil. No release to the environment is expected during transport and storage except in cases of spills. Once received by the customers, a variety of methods for storage and dispersal into compressors may be used. The majority of customers will store the finished oil containing the new substance in the sealed drums for direct transfer into the compressor sumps using pumps and/or faucets. If the pumps and faucets are handled properly with care, release to the environment is not expected aside from the loss of a few drops of finished oil per transfer. Alternatively, customers may transfer the finished oil to smaller containers, e.g., oil cans, using pumps and/or faucets for subsequent transfer into compressors.

The notifier claims that synthetic lubricants have a longer life than mineral oil based lubricants (2-3 times longer) and because of its resistance to oxidation, the draining interval for the lubricant is estimated to be up to 8000 hours. In comparison, the current practice for mineral oil based lubricants is to drain them every 500 hours. Therefore, the synthetic lubricant will be changed less often. The air compressor systems are closed systems, except for a high pressure air outlet and releases to the environment during normal operations are not expected.

A variety of methods for the collection of used oil are also possible. The likely system will be a combination of sump tank cleaner and centrifuge for renewing and purifying used oil. Clean oil is returned to the sumps and waste oil is stored in drums for final disposal. Used lubricants will normally be collected by a contractor for burning as a fuel. For the used oil that is unsuitable for burning due to contamination from large amounts of water, low flash petroleum products, sediment or other contaminants, disposal is by incineration.

Fate

The notifier does not expect release of the notified chemical to the environment will occur under normal operating conditions. However, losses may occur during transport of the drums and any further handling, as well as from the draining and charging of the air compressor systems. Any notified chemical that enters sewers/waterways is likely to become associated with sludge/sediment due to the chemical's high octanol-water partition coefficient and low water solubility.

Incineration the notified chemical is likely to produce oxides of carbon.

The biodegradability of the notified chemical was assessed at concentrations of 10 and 20 mg/L using the US EPA 'Shake Flask' method with an unacclimated sewage/soil inoculum. After 28 days, 33.2 and 28.9% of the carbon in the notified chemical was converted to CO_2, at initial test concentrations of 10 and 20 mg/L, respectively. Substances are considered readily biodegradable if 60% of the test material carbon is converted to CO_2 in 28 days. In addition, once biodegradation activity in initiated, defined as the point at which 10% of the test material carbon has been converted to CO_2, the 60% mark must be reached within 10 days. Therefore, the notified chemical is not readily biodegradable. Although, the notified chemical is not readily biodegradable under OECD guidelines, the notifier expects it to be inherently biodegradable. Microorganisms have been shown to initiate the biodegradation of sparingly soluble esters such as phthalate esters (1).

The bioconcentration factor of the notified chemical was calculated as > 20000 indicating a high bioconcentration potential. However, bioconcentration in aquatic organisms is unlikely as exposure of aquatic environments to the notified chemical is expected to be negligible. Also, a relatively high log K_{ow} of 9.5-15 indicates any bioconcentration would be very slow.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of MCP 1440

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2000 mg/kg	(2)
acute dermal toxicity	rabbit	LD_{50} > 2000 mg/kg	(3)
acute inhalation toxicity	rat	LC_{50} > 2.5 mg/L	(4)
skin irritation/corrosion	rabbit	slightly irritating non-corrosive	(5)
eye irritation	rabbit	slightly irritating	(6)
skin sensitisation	guinea pig	non-sensitising	(7)

9.1.1 Oral Toxicity (2)

Species/strain:	Sprague-Dawley rat
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	undiluted MCP 1440 at 2000 mg/kg was administered with a blunted needle
Clinical observations:	soft faeces, coloured nasal discharge and alopecia on fore paws were observed in two rats
Mortality:	nil
Morphological findings:	no gross pathological changes noted at necropsy
Test Method:	based on USEPA Health Effects Testing Guidelines (8) with one exeption (limit dose lowered to 2000 mg/kg instead of 5000 mg/kg)
LD_{50}:	> 2000 mg/kg
Result:	low acute oral toxicity in the rat

9.1.2 Dermal Toxicity (3)

Species/strain:	New Zealand White rabbit
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	undiluted MCP 1440 was applied to the shaved back of each animal and the test site was covered by 8-ply gauze followed by a rubber dam and surgical tape; the test site was wiped clean after patch removal 24 hours later
Clinical observations:	decreased feed consumption and faeces output, and soft faeces were observed in a few animals; one female showed weight loss between day 7 and 14
Method of administration:	undiluted MCP 1440 was applied to the shaved backs of each animal and the test site covered by 8-ply gauze followed by a rubber dam and surgical tape; the test site was wiped clean after patch removal 24 hours later

Clinical observations:	decreased feed consumption and faeces output, and soft faeces were observed in a few animals; one female showed a weight loss between day 7 and 14
Mortality:	nil
Morphological findings:	no gross pathological findings were noted at necropsy
Test Method:	based on USEPA Health Effects Testing Guidelines (8)
LD_{50}:	> 2000 mg/kg
Result:	low acute dermal toxicity in the rabbit

9.1.3 Inhalation Toxicity

The preliminary findings of an acute inhalation toxicity test were presented in a toxicity review (4). These are provided below.

Species/strain:	rats (unspecified strain)
Number/sex of animals:	2 groups, 5/sex/group
Observation period:	24 hours (group 1) and 14 days (group 2)
Method of administration:	atmosphere of MCP 1440 in breathing zone of animal chamber; single dose of 2.49 $\pm$ 0.09 mg/L (heated at 81°C) for 4 hours
Clinical observations:	no changes in body weights were noted during the observation periods; no other observations reported
Mortality:	nil
Morphological findings:	microscopic examination of pulmonary tissues is in progress
Test Method:	not stated
LC_{50}:	> 2.5 mg/L
Result:	low acute inhalation toxicity in the rat

9.1.4 Skin Irritation (5)

Species/strain: New Zealand White rabbit

Number/sex of animals: 3 males, 3 females

Observation period: 3 days

Method of administration: 0.5 ml of MCP 1440 was applied to a 2.5 cm^2 shaved area on the anterior and posterior flanks of each animal; the test sites were occluded with Webril patches followed by a rubber dam and surgical tape; anterior patches were removed after 1 hour (corrosion test) and posterior patches after 4 hours (irritation test); test sites were wiped clean after patch removal

Corrosion evaluation: both 1 and 4 hour occluded test sites showed no ulceration or necrosis immediately after patch removal or at 48 hours

Irritation evaluation - Draize scores (9):

Animal	***Time after decontamination (4 hour occlusion)***			
	30 min	***1 day***	***2 days***	***3 days***
Erythema				
1	1[i]	1	0	0
2	1	0	0	0
3	1	0	0	0
4	1	0	0	0
5	1	0	0	0
6	1	1	0	0
Oedema				
1	0	0	0	0
2	0	0	0	0
3	0	0	0	0
4	0	0	0	0
5	0	0	0	0
6	1	0	0	0

[i] see Attachment 1 for Draize scales

Test Method: based on USEPA Health Effects Testing Guidelines (8)

Result: slightly irritating, non-corrosive to rabbit skin

9.1.5 Eye Irritation (6)

Species/strain:	New Zealand White rabbits
Number/sex of animals:	3 males, 3 females
Observation period:	3 days
Method of administration:	0.1 ml of undiluted MCP 1440 was instilled into the left conjunctival sac of each animal and the eye lids held together for 1 second (the right eye served as control); all test eyes were stained with fluorescein at 24 hours

Draize scores (9):

	Time after instillation								
Animal	***1 day***			***2 days***			***3 days***		
***Cornea*:**	***o*[a]**	***a*[b]**		***o*[a]**	***a*[b]**		***o*[a]**	***a*[b]**	
1	0[i]	0		0	0		0	0	
2	0	0		0	0		0	0	
3	0	0		0	0		0	0	
4	0	0		0	0		0	0	
5	0	0		0	0		0	0	
6	0	0		0	0		0	0	
Iris									
1	0			0			0		
2	0			0			0		
3	0			0			0		
4	0			0			0		
5	0			0			0		
6	0			0			0		
Conjunctiva	***r*[c]**	***c*[d]**	***d*[e]**	***r*[c]**	***c*[d]**	***d*[e]**	***r*[c]**	***c*[d]**	***d*[e]**
1	3	1	0	1	1	0	1	0	0
2	2	1	1	1	1	0	0	0	0
3	2	1	0	1	0	0	0	0	0
4	1	1	1	0	0	0	0	0	0
5	0	0	1	0	0	0	0	0	0
6	0	0	1	0	0	0	0	0	0

[i] see Attachment 1 for Draize scales
[a] opacity [b] area [c] redness [d] chemosis [e] discharge

Test Method: based on USEPA Health Effects Testing Guidelines (8)

Result: diffuse conjunctival redness, discharge and slight chemosis were observed at 1 and 24 hours; all animals were normal by 72 hours except one with slight redness of the conjunctivae; the total Draize scores were 9.7, 5.3, 1.7 and 0.3 at 1, 24, 48 and 72 hours, respectively; the mean score calculated from the 24, 48 and 72 hour readings was 0.7 for conjunctival redness and was 0.3 for chemosis; no effects on the cornea or iris

were observed; the test substance was a slight eye irritant in rabbits

9.1.6 Skin Sensitisation (7)

Species/strain: Dunkin Hartley albino guinea pig

Number of animals: 4 range-finding animals (2/sex), 20 test animals (10/sex), 10 control animals (5/sex), 20 positive control animals (10/sex)

Primary irritation: 4 animals were treated topically with 0.4 ml of 25, 50 or 75% test substance (w/w in Squibb Mineral Oil (SMO)) for 6 hours under occluded patches; skin reactions were assessed after 22 hours; the highest non-irritating concentration was determined to be 50%; 75% test substance produced slight irritation

Induction procedure: 0.3 ml of test substance (75% w/w in SMO) was applied by occluded patch (6 hours) to the test guinea pigs once a week for 3 weeks; half the positive control animals were treated with 0.4 ml of 2,4-dinitrochlorobenzene (DNCB)(0.05% w/v in 80% ethanol); one test animal was found dead during induction phase, necropsy showed no treatment-related cause

Challenge procedure: 16 days after the last induction dose 0.3 ml of test substance (50% w/w in SMO) was applied to the test and control animals; all positive control animals were treated with DNCB (0.05% w/v in acetone)

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hrs****	***48 hrs****	***24 hrs***	***48 hrs***
50%	0/19**	0/19	0/10	0/10

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

Test Method: based on the Ritz and Buehler method (10) and OECD Guidelines for Testing Chemicals No: 406 (11); challenge applications were made 16 days after induction instead of 14 days due to inclement weather

Result:	very slight irritation was observed in one animal after induction exposure; after challenge exposure, 3 treated animals and 5 naive control animals had slight erythema; delayed dermal hypersensitivity was shown in the positive control group; the test substance was not found to be a skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (12,13,14,15)

Species/strain:	rat, Sprague-Dawley
Number/sex of animals:	main study 80 (10/sex/dose), recovery group 40 (10/sex/dose)
Method of administration:	the test substance was applied undiluted to the clipped backs of each animal; animals were fitted with cardboard Elizabethan collars to prevent ingestion of test substance (exposure sites were left uncovered)
Dose/Study duration::	10 animals of each sex were given 0, 125, 500 or 2000 mg/kg test substance 5 days a week for 4 weeks and sacrificed thereafter; an additional 10 animals of each sex were given 0 or 2000 mg/kg test substance for the same period and sacrificed after a 14 day recovery period
Clinical observations:	treatment-related effects were observed in the 2000 mg/kg/day group; perineal staining was seen in 5 females and 1 male; body weight gain of males was significantly lower than that of the control group; after the recovery period, both males and females had lower body weights than the control group
Skin irritation:	desquamation was observed in all groups (including controls) from 2 weeks onwards

Draize scores:

	Mean skin irritation scores							
	Control		125 mg/kg		500 mg/kg		2000 mg/kg	
Week	e[a]	o[b]	e[a]	o[b]	e[a]	o[b]	e[a]	o[b]
1	0[i]	0	0	0	0	0	0	0
2	0.5	0	0.7	0	0.9	0	1.1	0
3	0.7	o	1.1	0	1.2	0	1.3	0
4	0.8	0	1	0	1.3	0	1.2	0
5	0.6	0	1	0	1.1	0	1.4	0
6	0.3	0					0.3	0
7	0.6	0					0.6	0

[a] erythema [b] oedema
[i] see attachment 1 for Draize scales

Clinical chemistry/Haematology: some haematology parameters, including red blood cell (RBC) count, haemoglobin (Hb), mean corpuscular volume (MCV) and mean corpuscular haemoglobin (MCH), were significantly changed in the recovery group, however, the mean values were within the normal ranges derived from the historical data; serum glucose levels were significantly decreased in both male and female rats, while alanine aminotransferase (ALT), total bilirubin and triglyceride levels were significantly increased, but these changes were absent after 2 weeks recovery; after 2 weeks recovery, serum globulin level of the treated group was significantly higher than that of the control group

Necropsy/Histopathology: at necropsy, crusts/scabs on the treated skin were found in 3 male and 2 female rats administered 2000 mg/kg/day; absolute liver and kidney weights were increased in the high dose males and females and the mid-dose females, but these changes were not detected in the recovery group; a dose-related increase in the incidence of acanthosis with hyperkeratosis of the epidermis, sebacious gland hyperplasia and dermal inflammation of the treated skin was observed in all treated groups; the incidence and severity of the skin histological lesions were slightly reduced after 2 weeks recovery; diffuse hepatocellular hypertrophy was seen in both male and

	female rats administered 2000 mg/kg/day, but the liver lesions were not observed in the recovery group
Test Method:	based on OECD Guidelines for Testing Chemicals No: 410 (16); it was noted that individual animal data were not provided for any of the study parameters
Result:	the study showed that the target organ of toxicity in rats following repeated dermal exposure was the liver; because hepatocellular hypertrophy was not observed in the 500 mg/kg/day females, the increase in absolute liver weight was not considered to be treatment related

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (17)

Strains:	*Salmonella* strains TA 98, TA 100, TA 1535, TA 1537 and TA 102
Concentration range:	95, 285, 950, 2850 or 9500 µg/plate
Procedure:	strains were cultured with MCP 1440 in the absence or presence of rat liver S9; DMSO was used as a solvent control, and 2-aminoanthracene, 2-nitrofluorene, 9-aminoacridine, N-methyl-N'-nitro-N-nitrosoguanidine and mitomycin C were used as positive controls
Test Method:	plate -incorporation method in accordance with OECD Guidelines for Testing Chemicals No: 471 (18)
Result:	there were no significant increases in the number of revertant colonies in the treated plates compared to controls; the positive controls produced marked increases in the number of revertant colonies in all the test strains; under the test condition, MCP 1440 was not mutagenic in the *Salmonella typhimurium* reverse mutation assay

9.3.2 Chromosomal aberrations in cultured Chinese Hamster Ovary (CHO) cells (19)

Procedure:	CHO cell cultures were treated with MCP 1440 in the presence or absense of rat liver S9 according to the treatment regime described below; acetone was used as negative control, and mitomycin C and cyclophosphamide were used as positive controls
Experiment 1:	
without S9	doses: 0.018, 0.027, 0.042, 0.065, 0.10 µL/mL; treatment time 4 hours; harvest time 20 hours
with S9	same doses; treatment time 20 hours; harvest time 20 hours
Experiment 2:	same as experiment 1 with additional harvest time of 44 hours
Test Method:	based on OECD Guidelines for Testing Chemicals No: 473 (20)
Result:	no significant or dose-related increase in the incidence of chromosomal aberration was produced by MCP 1440; significant increases in chromosomal aberration were observed in the positive controls; MCP 1440 was not clastogenic in the CHO *in vitro* chromosomal aberration assay

9.5 Overall Assessment of Toxicological Data

Based on the toxicity studies provided by the company, MCP 1440 was of low acute oral and inhalation toxicity in rats and low dermal toxicity in rabbits. It was a slight skin and eye irritant in rabbits. It was not a skin sensitiser in guinea pigs. When rats were treated dermally with 125-2000 mg/kg/day for 28 days, the notified chemical produced local skin irritation and reversible hepatocellular changes in the 2000 mg/kg/day dose group. However, there was no treatment-related effects at the dose of 125 and 500 mg/kg/day. The notified chemical was not mutagenic in a bacterial reverse mutation assay *in vitro* and did not cause chromosomal aberration in CHO cultures.

Based on the toxicological data provided the notified chemical would not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (21).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Summary of the ecotoxicity of MCP 1440

Test	*Species*	*Outcome*	*Reference*
acute toxicity (in oil-water media)	rainbow trout	96 hour LOEC > 5008 mg/L	(22)
acute toxicity	*Daphnia magna*	48 hour LOEC > 8.3 mg/L	(23)
algal growth inhibition	*Selenastrum capricornutum*	72 hour EC_{50} > 27 mg/L	(24)

The rainbow trout toxicity experiment was conducted in an oil-water system using a method designed to maintain the oil in a dispersion of small droplets throughout the water column. With a calculated log octanol-water partition coefficient of 9.5-15, it is expected that the chemical would partition almost exclusively into the oil droplets. Treatment solutions were cloudy, likely the result of an emulsion formed between the oil and water. Analytical measurements of solutions showed highly variable concentrations of terephthalate ester from 700 mg/L up to 20000 mg/L in the 5008 mg/L (nominal) treatment, likely dependent on the distribution of oil droplets. As no adverse effects were observed in any treatment, the 96 hour LOEC was > 5008 mg/L (nominal), however, the variable analytical measurements cast considerable doubt on the validity of this result.

Analytical measurements of water samples in the *D. magna* experiment showed that all treatments were below the limit of quantitation of 8.3 mg/L despite intended nominal concentrations of up to 5100 mg/L. As the water solubility of the phthalate ester was calculated as 0.026-0.68 µg/L, it is unlikely concentrations even approached the limit of quantitation. Since no statistically significant adverse effects were observed in any treatment, the 48 hour LOEC was greater than the limit of quantitation of 8.3 mg/L.

The algal growth inhibition test produced similar results. Analytical measurements found all treatments to be below the limit of quantitation of 27 mg/L even for the highest nominal concentration of 5008 mg/L. Measurements of percent growth inhibition were variable with growth enhancement occurring in several treatments over the 72 hour experiment. Based on the results presented, the 72 hour EC_{50} was greater than 27 mg/L.

Acute and chronic toxicity studies (25,26) with other phthalate esters indicated that lower molecular weight esters with alkyl chains < 4 carbon atoms tended to be toxic to a range of aquatic organisms at concentrations > 0.2 mg/L. Those esters with chains lengths > 6 carbon atoms showed no acute or chronic toxicity at concentrations up to their respective solubilities in water (≤ 1.1 mg/L). The notified chemical has alkyl chain lengths of 11-14 carbon atoms.

The results indicate that the notified chemical is non-toxic to the organisms tested up to the limit of its solubility. Because of its extremely low water solubility, it is not expected to be toxic to aquatic organisms at concentrations likely to be found in waterways.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Releases of the notified chemical to sewers are not expected under normal operating conditions and any chemical present in the aquatic environment is unlikely to be at levels that result in adverse effects. Therefore, the notified chemical is unlikely to present a significant hazard to the environment from its proposed use due to the expected low environmental exposure and its low environmental effects.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (21). The toxicological profile of the chemical suggests that it is unlikely to produce acute toxic effects upon ingestion and dermal contact. Based on animal experimental data the toxicological hazards associated with the chemical will be slight skin and eye irritation as well as possible liver effects upon repeated dermal exposure. It should be noted however, that liver effects in rats were observed at a dose level of 2000 mg/kg/day and were reversible.

Worker exposure is expected to be limited to charging and draining operations. Exposure may also occur during transport and storage if an accidental spillage occurs, although this is unlikely given the type of containers used. As the draining interval for the lubricant is 8000 hours, the frequency of exposure will be low.

Whilst the compressors are in operation oil mist or vapour may be generated. However, as the chemical is not volatile (vapour pressure is 4.1×10^{-4} Pa at 25°C), inhalational exposure will be negligible. Possible routes of exposure will therefore be limited to skin and eye contact. Under normal use conditions protective gloves and goggles will be worn which will reduce the risk of skin and eye irritation. It is also unlikely during normal operations that workers will be exposed repeatedly to levels high enough to cause systemic effects.

When used in the proposed manner, public exposure to the notified chemical is expected to be negligible. In addition, the notified chemical is of low toxicity by oral or dermal administration in rats and not mutagenic or clastogenic *in vitro*. The proposed use of the notified chemical is not expected to pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to MCP 1440 the following guidelines and precautions should be observed:

- if engineering controls and work practices are insufficient to reduce exposure to MCP 1440 to a safe level, then the following personal protective equipment which conforms to Australian Standard (AS) or Australian/New Zealand Standard (AS/NZS) should be worn;

  wide vision goggles with indirect ventilation, face shield or hood should be selected and fitted in accordance to AS 1336 (27) to comply with AS/NZS 1337 (28),

  industrial clothing conforming to the specifications detailed in AS 2919 (29),

  impermeable gloves or mittens conforming to AS 2161 (30),

  all occupational footwear should conform to AS/NZS 2210 (31);

- spillage of the notified chemical should be avoided;

- 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 MCP 1440 was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (32).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of MCP 1440 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

1. Gibbons, J. A. & Alexander, M. 1989, 'Microbial degradation of sparingly soluble organic chemicals: Phthalate esters', *Environ. Sci. Toxic. Chem.* **8:** 283-291.

2. Study No: 65712, *Acute Oral Toxicity of MCP 1440 in the Sprague-Dawley Rat*. Stonybrook Laboratories Inc, Princeton, NJ, 1994.

3. Study No: 65713, *Acute Dermal Toxicity of MCP 1440 in the New Zealand White Rabbit*. Stonybrook Laboratories Inc, Princeton, NJ, 1994.

4. Bailey, P. T., *Assessment of Toxicokinetics of MCP 1440*. Stonybrook Laboratories Inc, Princeton, NJ, 1994.

5. Study No: 65715, *Acute Dermal Irritation/Corrosion of MCP 1440 in the New Zealand White Rabbit*. Stonybrook Laboratories Inc, Princeton, NJ, 1994.

6. Study No: 65714, *Acute Occular Irritation of MCP 1440 in the New Zealand White Rabbit*. Stonybrook Laboratories Inc, Princeton, NJ, 1994.

7. Study No: 65718, *Seven Week Epicutaneous Delayed Contact Hypersensitivity Study in Guinea Pigs (Buehler Sensitization Test) of MCP 1440*. Stonybrook Laboratories Inc, Princeton, NJ, 1994.

8. Environmental Protection Agency (US), 40 CFR Part 798, EPA Health Effects Testing Guidelines, 1985.

9. Draize J H. 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US,* **49,** 1959.

10. Official Journal of the European Communities, No. L 383A/134, 29 December 1992.

11. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of chemicals - Skin Sensitisation* No: 406, 1981.

12. Study No: 65720, *Systemic Toxicity Study of MCP 1440 Administered Dermally to Rats for 28 Days*. Stonybrook Laboratories Inc, Princeton, NJ, 1994.

13. Study No: 65720CA, *Serum Chemistry Data for a Systemic Toxicity Study of MCP 1440 Administered Dermally to Rats for 28 Days*. Stonybrook Laboratories Inc, Princeton, NJ, 1994.

14. Study No: 65720HA, *Hematology Data for a Systemic Toxicity Study of MCP 1440 Administered Dermally to Rats for 28 Days*. Stonybrook Laboratories Inc, Princeton, NJ, 1994.

15. Study No: 65720P, *Systemic Toxicity Study of MCP 1440 Administered Dermally to Rats for 28 Days - Gross and Microscopic Pathology*. Research Pathology Services, New Britain, PA, 1994.

16. OECD Guidelines for Testing of chemicals - *Repeated Dose Dermal Toxicity* No: 410, 1981.

17. Study No: 65716, *Ames Salmonella/Mammalian Microsome Mutagenesis Assay with MCP 1440*. Stonybrook Laboratories Inc, Princeton, NJ, 1994.

18. OECD Guidelines for Testing of chemicals - Salmonella typhimurium, *Reverse Mutation Assay* No: 471, 1983.

19. Study No: 65717, *Assay for Induction of Chromosomal Aberrations in Cultured Chinese Hamster Ovary (CHO) Cells by MCP 1440*. Stonybrook Laboratories Inc, Princeton, NJ, 1994.

20. OECD Guidelines for Testing of chemicals - *In vitro Mammalian Cytogenetic* Test No: 473, 1983.

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

22. Study No: 65721, *Static 96-Hour Acute Toxicity of MCP 1440 to Rainbow Trout*. Stonybrook Laboratories Inc, Princeton, NJ, 1994.

23. Study No: 65722, *Static 48-Hour Acute Toxicity Study of the Water Accomodated Fraction (WAF) of MCP 1440 to Daphnia magna*. Stonybrook Laboratories Inc, Princeton, NJ, 1994.

24. Study No: 66309, *Static 72-Hour Inhibition Study of the WAF of MCP 1440 to Selenastrum capricornutum*. Stonybrook Laboratories Inc, Princeton, NJ, 1995.

25. Adams, W. J., Biddinger, G. R., Robillard, K. A. & Gorsuch, J. W. 1995, 'A summary of the acute toxicity of 14 phthalate esters to representative aquatic organisms', *Environmental Toxicology and Chemistry* **14(9):**1569-1574.

26. Rhodes, J. A., Adams, W. J., Biddinger, G. R., Robillard, K.A. & Gorsuch, J. W. 1995, 'Chronic toxicity of 14 phthalate esters to *Daphnia magna* and rainbow trout (*Oncorhynchus mykiss*)', *Environmental Toxicology and Chemistry* **14(11):**1967-1976.

27. Australian Standard 1336-1982, Eye protection in the Industrial Environment. Standards Association of Australia Publ., Sydney, 1982.

28. Standards Australia/Standards New Zealand 1992, *Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.

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

30. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves),* Standards Association of Australia Publ., Sydney.

31. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear,* Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.

32. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets* [NOHSC:2011(1994)], Australian Government Publishing Service, 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