File No: NA/575

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Notified chemical in M-1999

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Notified chemical in M-1999

1. APPLICANT

Tretolite Pty Limited c/o Clayton Utz of 1 O'Connell Street SYDNEY NSW 2000 and Lubrizol International Inc of 28 River Street SILVERWATER NSW 2141 have jointly submitted a standard notification statement in support of their application for an assessment certificate for the notified chemical in M-1999.

2. IDENTITY OF THE CHEMICAL

Claims were made and accepted for certain Schedule data requirements to be exempt from publication in the Full Public Report. The data items were:

chemical name;
CAS number;
molecular and structural formulae;
molecular weight;
spectral data;
purity;
percent weight of impurities;
use, manufacture, and import volume; and
method of detection.

Marketing Name: M-1999

3. PHYSICAL AND CHEMICAL PROPERTIES

The notifier submitted data on M-1999, which contains the notified chemical and data on an analogue compound.

	M-1999	analogue compound
Appearance at 20°C and 101.3 kPa:	clear amber-coloured liquid	no data provided

Boiling Point:	> 200°C (see comments below)	223 -240°C
Specific Gravity:	0.84	0.813
Vapour Pressure:	no data provided	3.9
Water Solubility:	no data provided (see comments below)	no data provided
Viscosity:	no data provided	2.5 at 38°C
Partition Co-efficient (n-octanol/water):	log K_{ow} 3.58 (see comments below)	no data provided
Hydrolysis as a Function of pH:	no data provided (see comments below)	no data provided
Adsorption/Desorption:	no data provided (see comments below)	no data provided
Dissociation Constant:	no data provided (see comments below)	no data provided
Flash Point:	no data provided	82°C
Flammability Limits:	no data provided	no data provided
Autoignition Temperature:	no data provided	no data provided
Explosive Properties:	no data provided	lower limit at 150°C: 0.6 upper limit at 150°C: 5.1
Reactivity/Stability:	no data provided	no data provided

Comments on Physico-Chemical Properties

No quantitative data on water solubility was submitted with the notification, although subsidiary information - unsupported by test reports or other data - communicated by the notifier indicated *"that the substance exhibits little if any water solubility"*. In the reports (also supplied as subsidiary information) detailing the ecotoxicity tests conducted against Grass shrimp and Sheepshead minnow in sea water the test material was noted to be insoluble at all concentrations down to 3.2 mg/L. The reports indicated that despite use of solubilising agents, the test material did not fully dissolve or disperse, and that the majority of the

substance remained floating on the surface of the water throughout the duration of the test procedures. It is possible that this is a consequence of the high salinity (approximately 30 g/L) which can "salt out" sparingly soluble organic compounds.

The solubility may be estimated using accepted approaches based on the measured value of the n-octanol/water partition coefficient, and Lyman et al (Lyman et al., 1982) document a number of such predictive equations for a variety of chemical classes. Unfortunately there is no equation in this compilation specific for the notified chemical. Using the relevant equation for the closest structural analogues, gives an estimated water solubility (at 25°C) of around 8.2 mg/L. This is an appreciable value, and because of deficiencies in the chosen model, it may underestimate the true water solubility. A more generalised equation is also given by Lyman et al (Lyman et al., 1982) which is applicable to a large range of organic chemicals containing both polar and non-polar functionalities (equation 2-14 of (Lyman et al., 1982)). The estimated water solubility given by this equation is 64 mg/L. It should be noted that both these calculated solubilities are greater than the lowest concentration (3.2 mg/L) at which solubility problems were encountered in the ecotoxicity tests described below.

The notifier indicated that the notified chemical is very stable to hydrolytic degradation in the environmental range, typically between pH 4 and 9.

A full test report on the determination of the octanol/water partition coefficient was provided. This test was performed according to EEC/OECD Test Guideline 117 (Organisation for Economic Co-operation and Development, 1995-1996) at a facility complying with OECD Principles of Good Laboratory Practice. The resultant Log P_{ow} of 3.58 is in accord with the general chemical composition and structure. Because of the nature of the chemical, it is possible that it would adsorb quite strongly to organic material in the environment.

The notified chemical has no strongly acidic or basic properties in an aqueous environment, and is not expected to dissociate or to protonate forming ionic species under the usual environmental conditions.

4. PURITY OF THE CHEMICAL

Degree of Purity: high

5. USE, VOLUME AND FORMULATION

M-1999 containing the notified chemical will be imported as a component of a formulated catalyst modifier used in the petrochemical industry.

Between one to ten tonnes of M-1999 will be imported annually over the next five years.

6. OCCUPATIONAL EXPOSURE

M-1999 containing the notified chemical will be imported as a component of formulated catalyst modifier in 20 tonne isotanks or intermodal tanks. The isotanks are transported by railcars or trucks from the dockside to the refineries, where they are stored and used. During normal working conditions, workers are unlikely to be exposed to the notified chemical during transport and storage.

At the refinery, the formulated catalyst modifier is pumped from the isotank into a catalyst reactor through dedicated pumping lines. Pumping lines and isotanks are flushed with oil, which is fed into the reactor. The notifier estimated that two personnel would be involved in the process of activating the catalyst. The activation process is carried out using an enclosed automated system. During this process, worker exposure to the notified chemical is considered to be low. However, there is potential for workers to be exposed to the notified chemical when fitting and disconnecting lines during transfer of the notified chemical into the reactor. If exposure occurs it would most likely be by dermal route as opposed to the inhalation route. When fitting and disconnecting lines, workers are to wear personal protective equipment, including long sleeved shirt and neoprene or nitrile gloves as a minimum requirement. The work area should also be well ventilated to minimise inhalation exposure to the notified chemical.

When the catalysts are no longer usable, they are sent to a recycling facility. Ceramic materials from the spent catalysts are disposed of in a landfill area.

7. PUBLIC EXPOSURE

Following import, the formulated catalyst modifier containing the notified chemical will be only available to the petrochemical industry.

Public exposure may occur during transport accident or in the case of a refinery fire during storage of the formulated catalyst modifier containing the notified chemical. However, the clean up, disposal practices and fire-fighting measures described in the Material Safety Data Sheet (MSDS) provides sufficient information to enable emergency services to minimise public exposure during spill or fire explosion.

8. ENVIRONMENTAL EXPOSURE

Release

The catalyst modifier containing the notified chemical will be used only at oil refineries, and release to the general environment is expected to be very small. Hydrotreating units at petroleum refineries typically contain 4 to 5 tonnes of catalyst. Each regeneration requires the use of approximately 250 kg of the catalyst modifier which is pumped through a chemically resistant hose from the iso-tank directly to the catalyst bed where the catalyst material is activated through raising the temperature of the bed over a period of several hours.

The excess catalyst modifier is apparently not removed from the bed, but left in place till the hydrotreatment process is restarted, and residuals from the modifier presumably leave the reactor with the product stream(s). However, it is anticipated that the notified chemical reacts specifically with the catalyst components (probably noble metals) and consequently is substantially destroyed (or removed from the solution) during the activation process.

Any spills of the catalyst modifier resulting from accidents or leaks in the transfer equipment would be contained by bunding, and the spilt material either recovered for subsequent use or sent to the refinery's effluent treatment facility. During effluent treatment most of the notified chemical would be expected to become assimilated with other hydrocarbon wastes, and would be either sent to an oil recycling company or destroyed through incineration. A small quantity of the material may remain in the aqueous phase after waste treatment, and this would be discharged with the plant effluent, most likely into a sewerage system. However, in this case the residual material would associate with suspended organic matter, and would eventually become assimilated with sediments.

After the catalyst beds have reached the end of their useful lives, they are sent to a recycling facility for recovery of exotic metals. The ceramic substrate is disposed of into landfill. There is very little likelihood of any of the notified chemical remaining in these spent beds, and no release is expected as a consequence of disposal of old catalyst.

Fate

As mentioned above the notified chemical is destroyed during the activation process, although small quantities may be assimilated into the product streams. Consequently, the residual notified chemical could be expected to be burnt with the fuel and destroyed.

In the event of any accidental release of the material to either the soil or water compartment, it is expected that it would quickly become associated with natural organic matter, and consequently become assimilated into soils and sediments.

The material is not readily biodegradable, and limited details of a test on biodegradation under aerobic conditions conducted according to the protocol OECD 301-D (Organisation for Economic Co-operation and Development, 1995-1996) indicate only 18% biodegradation over a 28 day period. However, it is expected that the compound would slowly degrade over prolonged periods with production of gases such as oxides of carbon and nitrogen (aerobic conditions) and possibly ammonia and methane (anaerobic conditions).

The molecular weight of the compound is modest (approximately 200), and since the Log P_{ow} is 3.58, the chemical would have a high potential for bioaccumulation. However, when used in the indicated manner, the exposure of the new chemical is expected to be low.

9. EVALUATION OF TOXICOLOGICAL DATA

The studies below were conducted on a reaction mixture containing the notified chemical. The reaction mixture is known as M-1999. The notifier made claims for variation of the Scheduled

data requirements (acute inhalation studies, skin sensitisation, repeat dose toxicity and *in vivo* germ cell induction and *in vitro* chromosome damage) on the basis that the notified chemical is never isolated from the reaction mixture and therefore the pure substance is not available for testing. This claim for variation was accepted.

9.1 Acute Toxicity

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity males: females:	rat	 LD_{50} 590 mg/kg LD_{50} 540 mg/kg	(Costello, 1984b)
acute dermal toxicity	rabbit	200 < LD_{50} ≤ 2 000 mg/kg	(Costello, 1984a)
skin irritation	rabbit	corrosive	(Costello, 1984c)
skin corrosivity	rabbit	corrosive	(Romanelli, 1992)
eye irritation	rabbit	severe irritant	(Hershman, 1984)

9.1.1 Oral Toxicity (Costello, 1984b)

Species/strain: rat/Sprague-Dawley

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

Observation period: 14 days

Method of administration: gavage

Dose: 200, 500, 710, 1 000 and 2 000 mg/kg of test substance; doses of 200 and 500 mg/kg were administered as 10% w/v of M-1999 in corn oil; doses of 710, 1 000 and 2 000 mg/kg were administered as M-1999

Mortality: Males:

4-hour observation period

Dose (mg/kg):	
710	2 animals died
1 000	4 animals died
2 000	2 animals died

24 hour observation period

Dose (mg/kg):	710	one animal died
	1 000	3 animals died

Females:

4 hour observation period

Dose (mg/kg):	500	2 animals died
	710	all animals died
	1 000	4 animals died
	2 000	all animals died

24 hour observation period

Dose (mg/kg):	1 000	one animal died

Clinical observ tions: Males:

a) immediate effects

Dose (mg/kg):	200	all animals appeared normal
	500	all animals appeared normal
	710	all animals exhibited tremors
	1 000	all animals exhibited tremors
	2 000	all animals exhibited tremors

b) 4 hour observation period

Dose (mg/kg):	200	all animals appeared hyperactive
	500	all animals appeared hyperactive and exhibited tremors
	710	one animal appeared weak
	1 000	3 animals exhibited tremors

c) 24 hour observation period

Dose (mg/kg):	200	all animals appeared normal
	500	all animals appeared normal

	Females:	
		a) immediate effects
Dose (mg/kg):	200	all animals appeared normal
	500	all animals appeared normal
	710	all animals appeared sedated
	1 000	all animals exhibited tremors
	2 000	all animals exhibited tremors
		b) 4 hour observation period
Dose (mg/kg):	200	all animals exhibited tremors
	500	3 animals appeared sedated and exhibited tremors
	1 000	one animal exhibited tremors
		c) 24 hour observation period
Dose (mg/kg):	200	one appeared comatose;one appeared sedated and one appeared normal
	500	all animals appeared normal
Gross Patholog :	Males:	
		a) terminal kill
Dose (mg/kg):	200	no gross abnormalities
	500	no gross abnormalities
		b) decedents within 4 hours of treatment
Dose (mg/kg):	710	no gross abnormalities
	1 000	no gross abnormalities
	2 000	reddish mucoid material in the intestinal tract
		c) decedents within 24 hours of treatment
Dose (mg/kg):	710	haemorrhagic stomach
	1 000	haemmorrhagic stomach and blood-like fluid in the urinary bladder and a red mucoid material in the intestinal tract

	Females:	
		a) terminal kill
Dose (mg/kg):	200	no gross abnormalities
	500	no gross abnormalities
		b) decedents within 4 hours of treatment
Dose (mg/kg):	500	yellowish fluid in the intestinal tract
	710	haemorrhagic stomach and reddish mucoid material in the intestinal tract orange
	1 000	mucoid material in the intestinal tract
	2 000	reddish mucoid material in the intestinal tract and one animal also had haemorrhagic stomach
		c) decedents within 24 hours of treatment
Dose (mg/kg):	1 000	haemorrhagic stomach and orange mucoid material in the intestinal tract

Test method: according to the Environmental Protection Agency Health Effects Testing Guidelines (40 CFR, Section 163-81-1 Federal Register), which is similar to OECD test guideline (Organisation for Economic Cooperation and Development, 1987c)

LD_{50}: males: 590 mg/kg
females: 540 mg/kg

Result: the notified chemical was of low acute oral toxicity in rats

9.1.2 Dermal Toxicity (Costello, 1984a)

Species/strain: rabbit/New Zealand White

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

Observation period: 14 days

Method of administration: 200 or 2 000 mg/kg of test substance held under occlusive dressing; after 24 hours, excess material was wiped away

Mortality:		Males:	
	Dose (mg/kg):	2 000	4 animals died during the 24 hour treatment period
		Females:	
	Dose (mg/kg):	200	one animal died on day 7 and one male died on day 11
		2 000:	4 animals died during the 24 hour treatment period
Clinical observations:		Males:	
	Dose (mg/kg):	200	mild erythema was observed on day 4 which worsened to eschar in most animals by day 11
			loss of body weight in 2 animals on day 7 and in one animal in day 14
			4 animals appeared normal through out the study
		2 000	eschar was noted in one surviving animal after removal of dressing; this animal appeared hypoactive on day 1 through day 4, and appeared normal until the termination of the study; loss of body weight was observed on day 7
		Females:	
	Dose (mg/kg):	200	one animal had diarrhoea and another animal appeared bloated on day 6 and died on day 7; body weight loss was observed in 2 animals on day 7 and in one animal on day 11
		2 000	eschar was noted in one surviving animal after removal of dressing; this animal appeared hypoactive on day 1 through day 4, was hypersensitive to touch on day 5 and appeared normal from day 7 until the termination of the study; loss of bodyweight was noted on day 7

Gross Pathology:	Males:	
Dose (mg/kg):		a) terminal kill
	200	no gross abnormalities
	2000	no gross abnormalities
		b) decedents
	2 000	haemorrhagic lungs
	Females:	
		a) terminal kill
	200	no gross abnormalities
	2 000	no gross abnormalities
		b) decedents
	200	nasal discharge and mucoid enteritis
	2 000	haemorrhagic lungs

Test method: according to Environmental Protection Agency Health Effects Testing Guidelines (40 CFR, Section 163-81-2 Federal Register), which is similar to OECD test guideline (Organisation for Economic Cooperation and Development, 1987a)

LD_{50}: between 200 to 2 000 mg/kg

Result: the notified chemical was of moderate dermal toxicity in rabbits

9.1.3

9.1.4 Inhalation Toxicity

Study not conducted.

9.1.4 Skin Irritation (Costello, 1984c)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 6 (sex not stated)

Observation period: 3 days

Method of administration: 0.5 mL of test substance applied to the test site and held under occlusive dressing; after 4 hours residual test material was removed with dry gauze; the treated areas were examined for skin lesions and graded within 30 to 60 minutes of removal of dressing, and 24, 48 and 72 hours after treatment

Draize scores (Draize, 1959):

Time after treatment (days)	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6***
Erythema [(1)]						
4 hours	3	2	2	3	3	3
1	4[E]	4[E]	4[E]	4[E]	4[E]	4[E]
2	4[E]	4[E]	4[E]	4[E]	4[E]	4[E]
3	4[E]	4[E]	4[E]	4[E]	4[E]	4[E]
7	4[E]	4[E]	4[E]	4[E]	4[E]	4[E]
Oedema [(1)]						
4 hours	4	4	4	4	4	4
1	4	4	4	4	4	4
2	4	4	4	4	4	4
3	4	4	4	4	4	4
7	4	4	4	4	4	4

[(1)] see Attachment 1 for Draize scales
[E]- Eschar

Test method: according to Environmental Protection Agency Health Effects Testing Guidelines (40 CFR, Section 163.81-5 Federal Register), which is similar to OECD test guideline (Organisation for Economic Cooperation and Development, 1992))

Result: the notified chemical was corrosive to the skin of rabbits

9.1.5 Skin Corrosivity (Romanelli, 1992)

The skin corrositivity of the notified chemical was tested in fulfillment of the requirements set by the International Maritime Dangerous Goods (IMDG) Code which allows dermal irritation/corrosivity classification of the test material according to IMDG code (Packaging Group III) which is administered by the International Maritime Organisation (IMO).

Species/strain: rabbit/New Zealand White

Number of animals: 6 (sex not stated)

Observation period: 48 hours

Method of administration:	0.5 mL of test substance was applied to the back of rabbits and held under occlusive dressing; after 4 hours the site was wiped with deionised water; the treatment site was examined at 4, 24 and 48 hours after test substance application
Clinical Observation:	necrotic skin, severe oedema and/or well defined erythema-pallor were observed at the 4 hour observation time, and regress to eschar and slight to moderate oedema after 48 hours
Test method:	Department of Transportation , 49 CFR guidelines, similar to OECD guidelines (Organisation for Economic Cooperation and Development, 1992)
Result:	the notified chemical was corrosive to the skin of rabbits

9.1.6 Skin Sensitisation

Study not conducted.

9.1.7 Eye Irritation (Hershman, 1984)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	6 (sex not stated)
Observation period:	21 days
Method of administration:	0.1 mL of test substance was instilled into the conjunctival sac of one eye of each animal; the other eye served as the control
Unirrigated eyes:	moderate to severe irritation was observed on day 7 with slight irritation observed at day 21, lesions were mainly limited to the conjunctiva as follows: hair loss surrounding the eye due to excessive tearing and subsequent rubbing of the eye (sialodacryoadenitis); eyelids cemented closed by dried discharge; white to yellow-greenish pus-like exudate; and clear visible pits in the normally smooth corneal surface

Test method:	according to Environmental Protection Agency Health Effects Testing Guidelines (40 CFR, Section 163.81-4 Federal Register), similar to OECD test guideline (Organisation for Economic Cooperation and Development, 1987b)
Result:	the notified chemical was a severe irritant to the eyes of rabbits

Draize scores (Draize, 1959) of unirrigated eyes:

	Time after instillation																			
Animal	***1 day***			***2 days***			***3 days***			***4 days***			***7 days***			***14 days***			***21 days***		
Cornea [1]	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***
1	1		1	1		1	1		1	1		2	0		0	0		0	0		0
2	1		2	1		4	1		4	1		4	1		4	0		0	0		0
3	1		2	1		1	1		1	1		3	1		2	0		0	0		0
4	1		4	1		2	1		2	1		2	0		0	0		0	0		0
5	2		4	1		4	1		4	1		4	2		4	1		1	2		2
6	0		0	1		4	1		4	1		4	-		-	0		0	1		1
Iris [1]																					
1		0			0			0			0			0			0			0	
2		0			0			0			0			0			0			0	
3		0			0			0			0			0			0			0	
4		0			0			0			0			0			0			0	
5		0			0			0			0			0			0			0	
6		0			0			0			0			0			0			0	
Conjunctiva [1]	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	4	3	3	3	3	3	3	3	2	3	2	1	2	0	1	1	1	1	1	0
2	3	4	2	3	4	2	3	4	0	2	3	0	1	3	0	1	2	1	1	1	0
3	3	4	3	3	4	1	2	4	0	2	3	0	1	4	2	1	1	0	0	0	0
4	2	4	3	3	4	3	2	4	0	2	4	1	1	3	0	1	1	1	1	1	1
5	2	4	2	3	4	3	3	4	2	2	4	1	1	4	0	1	2	0	1	2	1
6	3	4	3	3	4	3	3	4	3	2	4	2	1	4	0	1	2	0	0	1	0

[1] see Attachment 1 for Draize scales o = opacity a = area of cornea r = redness c = chemosis d = discharge - = score not reported

9.2 Repeated Dose Toxicity

Study not conducted.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Thompson, 1997)

Strains:	*S typhimurium* TA1535, TA1537, TA 98 and TA100, and *E coli* WP2uvrA$^-$
Metabolic activation system:	liver microsomal fraction (S9) from rats pretreated with Aroclor 1254
Experimental design:	<u>experiment 1:</u> *S typhymurium* and *E coli* treated with 5 – 1 500 μg test substance/plate evaluated with or without metabolic activation vehicle control: acetone positive controls without metabolic activation: N-ethyl-N'-nitro-N-nitrosoguanidine (ENNG), 9-Aminoacridine (9AA) and 4-Nitroquinoline-1-oxide (4NQO) positive control with metabolic activation: 2-Aminoanthracene (2AA) <u>experiment 2:</u> experiment performed as described in experiment 1 except that *S typhymurium* and *E coli* were treated with 15 – 1 500 μg test material/plate evaluated with or without metabolic activation vehicle control plates produced revertant colonies within the normal range positive controls, with or without metabolic activation, produced significant increases in revertant colonies
Comment:	test substance exhibited toxicity at 1 500 μg/plate with all of bacterial strains both with and without

	metabolic activation; no significant increases in revertant colonies for any of the bacterial strains at any dose with or without metabolic activation;
Test method:	according to OECD guidelines (Organisation for Economic Cooperation and Development, 1983b), (Organisation for Economic Cooperation and Development, 1983a)
Result:	the notified chemical was considered not to be mutagenic in the bacterial strains tested with and without metabolic activation

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse

Study not conducted.

9.4 Overall Assessment of Toxicological Data

The studies above were conducted on a reaction mixture known as M-1999, containing the notified chemical. The notifier made claims for variation of the Schedule data requirements (acute inhalation studies, skin sensitisation, repeat dose toxicity and *in vivo* germ cell induction and *in vitro* chromosome damage) on the basis that the notified chemical is never isolated from the reaction mixture and therefore the pure substance is not available for testing. This claim for variation was accepted.

M-1999 exhibited low acute oral toxicity in rats: the LD_{50} for males was 590 mg/kg and for females 540 mg/kg. In an acute dermal toxicity test, M-1999 was moderately toxic to rabbits with an LD_{50} in the range of 200 to 2 000 mg/kg. M-1999 is an eye irritant, with corneal and conjunctival effects present in rabbits at 21 days. Necrotic skin was visible after a 4-hour treatment in the skin corrosivity test and severe oedema and/or well-defined erythema-pallor persisted for seven days in the skin irritation study.

M-1999 was not mutagenic in *Salmonella typhimurium* and *Escherichia coli* strains with or without metabolic activation.

M-1999 is toxic via the oral and dermal route, irritating to the eye, and corrosive to skin. M-1999 is not mutagenic to bacteria. Therefore, on the basis of the toxicological data provided, M-1999 would be classified as a hazardous substance (Toxic) in accordance with the NOHSC *Approved Criteria* (ref). The appropriate risk phrases are R24 – Toxic in contact with skin, R22 – Harmful if swallowed, R34 – Causes burns, and R36 – Irritating to eyes.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier and were conducted using a 90% solution of the notified chemical in kerosene. It is not documented whether all tests were carried out using OECD Test Methods, but the test reports provided for the acute toxicity to sheepshead minnow and to the grass shrimp were well documented and well presented, and appeared to follow accepted OECD Test Guideline principles.

Test	***Species***	***Results***		***Reference***
acute toxicity	rainbow trout *Oncorhynchus mykiss*	LC_{50} (96 hours):	13.4 mg/L	(Foster, 1990)
acute toxicity	sheepshead minnow *Cyprinodon variegatus*	LC_{50} (96 hours): NOEC:	12.0 mg/L 5.6 mg/L	(Kuc, 1997b)
acute toxicity	grass shrimp *Paleomonetes pugio*	LC_{50} (96 hours): NOEC:	9.5 mg/L 3.2 mg/L	(Kuc, 1997a)

* NOEC - no observable effect concentration

The tests on rainbow trout were conducted over a 96-hour period in filtered and de-chlorinated tap water at a temperature of 12± 2 ºC. The tests were run in duplicate, using one control and 10 test fish in each test. The nominal concentrations of M-1999 employed were 10, 18, 32, 56 and 100 mg/L. It was not stated in the report provided whether any difficulty with solubility of the test material was encountered, as was the case for the tests on sheepshead minnow and grass shrimp (conducted in sea water) discussed below. No mortality was observed in the control samples, but 95-100% mortality was observed within 24 hours at test concentrations greater than 32 mg/L. One fish surviving after 96 hours exposure at 18 mg/L was dark coloured, lethargic and showed other signs of stress.

The tests on sheepshead minnow were conducted over a 96-hour period in synthetic seawater with salinity between 30 and 31 gram per litre at a temperature of 17± 1 ºC and initial pH of 8.6. Five test dispersions were prepared containing the following nominal concentrations of test material: 3.2, 5.6, 10.0, 18.0 and 32 mg/L. The tests were conducted using 10 test fish per test with a control. The test material was noted to be insoluble, and the report indicated that despite use of solubilising agents that it did not fully dissolve or disperse. As mentioned, previously, this may have been a consequence of the high ambient salinity.

At a nominal exposure concentration of ≥ 18 mg/L, 100% fish mortality occurred after 24 hours; fish exposed to ≥ 10 mg/L demonstrated clear signs of distress, ie gulping air, erratic swimming and lethargy. In all test containers, dissolved oxygen levels remained above 6.5 mg/L throughout the test period, but the pH dropped to 8.3 after 96 hours.

The tests on grass shrimp were conducted under similar conditions (ie, test animal numbers, salinity, temperature, pH, dissolved oxygen and test duration) as those for the sheepshead minnow. Six test dispersions were prepared containing the following nominal concentrations of test material, 1.8, 3.2, 5.6, 10.0, 18.0 and 32 mg/L. At a nominal exposure concentration of 32 mg/L, 100% fish mortality occurred after 24 hours, and fish exposed to ≥ 5.6 mg/L demonstrated clear signs of distress, ie ceased or erratic swimming and quiescence.

The ecotoxicity results above may underestimate actual toxicity due to the problems with solubility encountered during the tests. However, the results indicate that the material is at least moderately toxic to both freshwater fish (rainbow trout) and saltwater fish (sheepshead minnow) and saltwater invertebrates (grass shrimp). Although no information was submitted on the effect of the notified chemical on algal growth, the toxicity of compounds of similar chemical nature indicate that the notified chemical may significantly inhibit the natural growth of algal organisms (Nabholz et al., 1993).

One of the joint notifiers indicated that the acute toxicity tests on Rainbow Trout gave an LD_{50} of 1,400 mg/L. No reports or other supporting evidence were provided so it must be assumed that these tests were conducted on the formulated catalyst modifier and not on the M-1999 used in the above tests.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

If any of the notified chemical were to be released to the soil or water compartment, it would adsorb to and become assimilated into the organic component of soils and sediments. The notified chemical is at least moderately toxic to the fish and invertebrate aquatic species against which it has been tested, and is possibly significantly more toxic to algae. However, given the exclusive use of the material within oil refineries under well-organised operational conditions, large releases to the water compartment are considered unlikely. The most probable route for the material to enter the environment would be as a consequence of accidents during transport to the refineries, or transfer from the on site storage (isotanks) to the catalyst beds. However in the majority of such circumstances the spilt material would be contained and destroyed through incineration or oil recycling activities.

The environmental hazard from the notified chemical is small when it is used in the proposed manner indicated by the notifier.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The experimental animal studies conducted on M-1999 indicated it was acutely toxic via the oral and dermal route. M-1999 was also irritating to the eye and corrosive to skin. It was not mutagenic to bacteria. On the basis of the toxicological data provided, M-1999 would be

classified as a hazardous substance (Toxic) in accordance with NOHSC *Approved Criteria* (National Occupational Health and Safety Commission, 1994a) and warrants the risk phrases: R24 – Toxic in contact with skin and R22 – Harmful if swallowed if present at ≥ 25%; R34 – Causes burns if present at ≥ 10%; and R36/38 – Irritating to eyes and skin if present at > 5 ≤ 10%.

However, M-1999 containing the notified chemical will be imported as a component of a formulated catalyst modifier at a concentration of less than 0.5%. This concentration is below the concentration cut off level for corrosive (causes burns) and irritant effects under the hazardous substances health effects criteria (10% and 5%, respectively). In addition, the formulated catalyst modifier contains M-1999 at a level below the concentration cut off level for acute lethal effects. At this concentration of M-1999, the formulated catalyst modifier is not a hazardous substance under the NOHSC Approved Criteria for Classifying Hazardous Substances (National Occupational Health and Safety Commission, 1994a).

Under normal working conditions, workers involved in transport and storage of the formulated catalyst modifier are unlikely to be exposed to the notified chemical and therefore occupational risk for these workers are considered to be low. However, there is potential for workers to be exposed to the notified chemical during transfer of the notified chemical into the reactor when fitting and disconnecting lines. To avoid potential dermal exposure when fitting and disconnecting lines, workers are to wear personal protective equipment, including long sleeves shirt and neoprene or nitrile gloves, as a minimum requirement. The work area should also be well ventilated to minimise inhalation exposure to the notified chemical.

Given the proposed use, the notified chemical present in the formulated catalyst modifier is not expected to present a significant risk to the public.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical in M-1999 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);

- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990);

- Impermeable gloves or mittens should conform to AS 2161.2 (Standards Australia, 1998);

- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

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

This MSDS was provided by Lubrizol International Inc 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 Lubrizol International Inc.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

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

16. REFERENCES

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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