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# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

#### **FULL PUBLIC REPORT**

**Z-16** 

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989*, 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 Human Services and Health.

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 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

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Director
Chemicals Notification and Assessment

#### **FULL PUBLIC REPORT**

**Z-16** 

# 1. APPLICANT

Lubrizol Australia, 28 River St, Silverwater, NSW 2141 has submitted a standard notification for assessment of Z-16.

#### 2. IDENTITY OF THE CHEMICAL

Z-16 has been classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (1) due to its potential to cause skin sensitisation. However, for commercial reasons, the chemical identity, methods of detection and determination, and spectral data have been granted exemption from publication in the Full Public Report and Summary Report. The conditions of this being permitted are:

- A descriptive generic name substituted phenol, be used to identify the substance in public reports and the MSDS,
- The relevant employee unions shall be informed of the conditions of use of Z-16,
- The full chemical name shall be provided to any health professionals in the case of a legitimate need where exposure to the chemical may involve a health risk,
- The full chemical name shall be provided to those on site who are using the chemical and to those who are involved in planning for safe use, etc. in the case of a legitimate need.
- The Director of NICNAS will release the full chemical name etc in the case of a request from a medical practitioner,
- Confidentiality will expire after a 3 year period,
- The chemical be identified as a sensitiser in the Health Effects Section of the MSDS, and that reference to its assessment by NICNAS be made on the MSDS,
- These conditions shall be published in the Chemical Gazette.

Other names: Z-16, substituted phenol

#### 3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C

and 101.3 kPa: dark brown, viscous liquid

Freezing point: < -23°C

**Boiling point:**  $94 - > 319^{\circ}\text{C}$  **Vapour pressure:**  $3 \times 10^{-3}\text{Pa}$ 

**Density:** 0.89749 (relative to water) at 20°C

Water Solubility: 0.0226 g/L at 20°C

**Partition coefficient** 

(n-octanol/water) log P<sub>ow</sub>: 1.89

Soil adsorption/desorption: not determined

Hydrolysis as a

function of pH: not expected to hydrolyse on the basis of chemical

structure

**Dissociation Constant** 

**pKa:** predicted to be about 14 on the basis of chemical

structure

Flash Point: 140°C (closed cup)

Flammability Limits: not applicable due to low vapour pressure and high

flash point

**Autoignition Temperature:** 266°C

**Explosive Properties:** none

Reactivity/Stability: not an oxidising agent

## Comments on the physico-chemical properties

Soil adsorption/desorption: As the notified chemical is relatively soluble, does not degrade and has a relatively low  $P_{ow}$  it could be mobile in the soil and potentially leach. However, it is stated that, in view of the intended use, the material should not be distributed in the environment.

# 4. PURITY OF THE CHEMICAL

Degree of purity: 99.2%

Toxic impurities: None

Non-toxic impurities:

(> 1% by weight): None

Additives/Adjuvants: None

#### 5. INDUSTRIAL USE

The notified chemical is to be used as an oil additive in the crankcase oil of diesel trucks.

It will be imported as a component (5 - 20%) of an oil additive package in 205 L steel drums at a rate of 50 tonnes for the first year rising to 200 tonnes in the fifth year.

#### 6. OCCUPATIONAL EXPOSURE

Typically, a performance additive package such as Lubrizol 4816 M which contains the notified chemical, contains anti-oxidants, corrosion inhibitors, antiwear agents, detergents and dispersants. Viscosity modifiers may be part of the package or may be added separately by the lubricant manufacturer.

Following transport by road or rail to the blend facilities of the oil industry, the drums are stored prior to lubricant manufacture. Typically, lubricant manufacture involves first charging the blending vessel with an oil blend. Then two blend plant operators transfer the oil additive package to the blend vessel either by decanting it into a drum dump trough or inserting a spear into the drum. In either case the additive package is pumped directly into the blend vessel through enclosed lines. Additional diluent oil is pumped into the blend vessel. This process is overseen by one operator and is typically computerised.

The blend is stirred for 1 - 2 hours and then about 0.5 L is sampled for analysis. When the blend is approved it is 'bottled' in 1 to 205 L containers for sale to workshops and retail outlets. Once the 'bottling' process is completed the various feed lines are flushed with diluent oil. The flushings are labelled and used in subsequent batches. The concentration of the notified chemical in the final product will vary between 0.4 and 3.2%.

It is stated that the above processes are carried out in closed systems.

Typically the blending process may continue for several days depending on the amount to be blended. In the first year this would mean a total processing time of 20 - 30 days.

Occupational exposure to the notified chemical may also occur when oil containing it is added to truck engines by vehicle assemblers or when the oil is being changed in garage workshops.

#### 7. PUBLIC EXPOSURE

The public may be dermally exposed to the notified chemical when using or disposing of engine oils. As noted below, oil changes by individuals represent 15% of the total (2).

## 8. <u>ENVIRONMENTAL EXPOSURE</u>

#### . Release

Apart from accidental spills, there should be no waste generated during lubricant manufacture. The lubrication oil will then be sold in bulk or as small packages to vehicle manufacturers, garages and the general public. The bulk containers are normally returned for reuse and the small packages disposed in the domestic garbage.

Disposal of the notified chemical will occur with the waste oil when vehicles oils are changed. Approximately 86% of vehicles have oil changes done by industry, garages etc., with less than 15% of oil changes done by individuals (2).

#### . Fate

The environmental fate of the notified chemical will be closely aligned with the environmental fate of the used engine oil.

Approximately 40% of the engine oil sold in Australia is consumed by burning during use and loss from leaks etc. As most oil is sold to industry, garages and other service centres (206 ML), most of the waste engine oil is collected or disposed of correctly. In Australia 96% of collected waste engine oil is used as fuel or incinerated, with little being recycled (2). The old practice of using waste oils as a dust suppressant is currently being phased out or is not practised by local councils and represents a very minor use (2).

The DIY market for oil sales in Australia is approximately 40 ML, with about 33 ML being used when individuals do an oil change (2). It is from this group that the majority of used engine oil reaches the environment. Only 5 ML is collected from individuals and households (figure for 1990), with the rest being disposed of in various ways (2). Assuming 40% of the oil used by the DIY market is consumed during use and that 5 ML is collected, then approximately 19 ML of waste oil enters the environment in various ways. The fate of this used oil is uncertain, either ending up in landfill, poured down the drain, disposed of on land to kill weeds or used to paint fences etc.

The notified chemical was tested for its biodegradability, using a Japanese test method which is similar to OECD test guideline 301C. This test used activated sludge from a domestic sewage plant in a closed bottle test and was performed at a concentration of 100 ppm and 30 ppm (nominal) for 28 days. The notified chemical was found to be not ready biodegradable. The test did show some degradation (1% over 28 days) which is so low that it is unclear whether the compound is inherently biodegradable.

The bioaccumulation potential of the notified chemical was investigated using a Japanese test method for the bioaccumulation and is equivalent to OECD test guideline 305C. The results show a bioaccumulation factor of between 215-495 for the low molecular weight material (mass number 346) and 62-111 for high molecular weight (374). These figures are relatively low and show that significant bioaccumulation is unlikely.

#### 9. EVALUATION OF TOXICOLOGICAL DATA

# 9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Z-16

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD <sub>50</sub> > 5000 mg/kg	(3)
Acute dermal (4) toxicity	Rabbit	$LD_{50} > 2000$ mg/kg	
Skin Irritation	Rabbit	slight irritant	(5)
Eye irritation	Rabbit	slight irritant	(6)
Skin sensitisation	Guinea-pig	sensitiser	(7,8)

# **9.1.1 Oral Toxicity (3)**

This study was conducted in accordance with OECD guideline No. 401 (9). Sprague-Dawley rats (5/sex) received a single dose of Z-16 by gavage at a dose level of 5000 mg/kg.

There were no deaths over the 14 day observation period. No significant changes in body weight were observed during the study and there were no significant changes for all tissues examined at necropsy on day 15.

Clinical signs were urogenital staining (wet or dry yellow) for all rats, soft stool in 8 rats, dried red staining around the nose in 2 rats and a single occurrence of wet yellow abdominal staining. All rats appeared normal by day 4 and remained so for the remainder of the study.

It can be concluded that the acute oral  $LD_{50}$  for the notified chemical in rats is > 5000 mg/kg.

## 9.1.2 Dermal Toxicity (4)

This study was conducted in accordance with OECD guideline No. 402 (10). New Zealand White rabbits (5/sex) received a single dose of 2000 mg/kg of Z-16 applied under a gauze patch held in place for 24 hours.

There were no deaths during the 14 day observation period, no significant body weight changes or clinical findings and no significant gross necropsy findings.

The notified chemical induced slight to moderate erythema and very slight to slight oedema in all rabbits. Very slight erythema and/or desquamation persisted through study termination for 7 animals.

It can be concluded that the acute dermal  $LD_{50}$  for the notified chemical in rabbits is > 2000 mg/kg.

# 9.1.3 Skin Irritation (5)

This study was conducted in accordance with OECD guideline No. 404 (11). New Zealand White rabbits (2 males, 4 females) received a dose of 0.5 mL of the notified chemical under a gauze patch for 4 hours.

No response was observed in one rabbit throughout the 72 hour observation period. Three rabbits exhibited slight erythema and 2 rabbits very slight erythema at 1 hour post-treatment. Two rabbits exhibited very slight erythema up to 72 hours, 2 rabbits exhibited very slight erythema only at 24 hours and the remaining rabbit exhibited very slight erythema only at 72 hours post-treatment.

The only oedema observed was very slight in 2 rabbits at 1 hour post-treatment.

It can be concluded that the notified chemical is a slight skin irritant in rabbits.

## 9.1.4 Eye Irritation (6)

This study was conducted in accordance with OECD guideline No. 405 (12). New Zealand White rabbits (3/sex) received a dose of 0.1 mL of the notified chemical directly into the cupped lower conjunctival sac of the right eye of each animal.

No effects on the cornea or iris were seen except for a moderate iris response in one animal at 1 hour post-treatment.

Conjunctival redness at 1 hour post-treatment was either moderate (5 rabbits) or slight (1 rabbit). Conjunctival redness at 24 hours was slight in all rabbits and this was also observed in 4 rabbits at 48 hours and 1 rabbit at 72 hours. No conjunctival redness was observed in 2 rabbits at 48 hours and in five rabbits at 72 hours.

Moderate chemosis (swelling) of the conjunctiva was observed in 1 rabbit at 1 hour post-treatment with the remaining rabbits exhibiting slight chemosis. Slight chemosis was observed in 4 rabbits at 24 hours, in 2 rabbits at 48 hours but was no longer present in any rabbit at 72 hours.

It can be concluded that the notified chemical is a slight eye irritant in rabbits.

#### 9.1.5 Skin Sensitisation (7,8)

Two studies were conducted in accordance with OECD guideline No. 406 (13) using a modified Buehler method with 10 guinea pigs (5/sex) of the Hartley strain in the test group.

Induction was carried out as 3 weekly 6-hour topical applications of either undiluted Z-16 (7) or 40% Z-16 in heavy mineral oil (8). In the study where undiluted Z-16 was used for induction, challenge with undiluted Z-16 was performed two weeks after the final induction. None of the test animals exhibited sensitisation but skin irritation was observed in control animals. Consequently rechallenge was performed with 1% Z-16 in ethanol and 25% Z-16 in mineral oil 11 days after challenge. At the 1% concentration, 5/10 animals were positive and at the 25% concentration 4/10 animals were positive.

In the study where 40% Z-16 was used for induction, challenge with 25% Z-16 in mineral oil was performed two weeks later. In this case no animals exhibited a positive response.

It can be concluded that the notified chemical is a sensitising agent in guinea-pigs.

# 9.2 28-Day Repeated Dose Oral Toxicity (14)

This study was conducted in accordance with OECD guideline No. 407 (14). Sprague-Dawley rats (5/sex/dose) received doses of 0, 81, 243 and 810 mg/kg/day by gavage. An additional five rats per sex in the zero and high dose groups were allowed a 14 day recovery period from day 29. However, as the highest dose resulted in mortality after 9 days, this was reduced to 405 mg/kg/day on day 15 for the remainder of the study.

By day 14 eight animals had died in the highest dose group and a further 2 were killed as moribund after reduction of the dose to 405 mg/kg/day. One animal in the 243 mg/kg/day dose group was killed as moribund on day 25.

No significant effects of the notified chemical on body weight or body weight gain were observed during the study.

No biologically significant changes in haematology parameters or urinalysis parameters were observed during the study.

The primary toxic findings were an effect on coagulation as noted by internal haemorrhage and increased prothrombin and activated partial thromboplastin times, and liver toxicity as noted by increased liver weight and microscopic lesions. Increased cholesterol levels were seen only in female animals, also indicating impaired liver function.

The effects on coagulation occurred in the mid and high dose males and females and were not observed in the recovery animals.

On gross necropsy, haemorrhage due to the notified chemical was observed in body cavities - thorax, neck, abdomen and retroperitoneum and in organs and tissues - skin, testes, epididymides, thymus and salivary glands. Haemorrhages were predominantly observed in animals found or killed as moribund and were largely confined to the high dose group.

Enlargement of the liver as confirmed by organ weights was dose-related and reversed in male but not female rats at the end of the recovery period.

Dose-related microscopic lesions were observed in the liver, salivary glands, thymus and testes. Lesions observed in the spleen were chemical-related but not dose-related. Treatment-related liver changes were hepatocellular fatty change, portal inflammation, necrosis and haemorrhage. Hepatocellular fatty change was not reversible in male rats, but was reversible in female rats. There was a slight increase in severity in low dose animals compared to controls but the more severe effects occurred in mid and high dose animals. Microscopic lesions in the thymus (haemorrhage, thymocyte depletion and necrosis) were observed only in high dose males and females and were reversible. Also reversible were lesions in the testes in high dose males. Lymphoid hyperplasia and red pulp depletion in the spleen were not dose-related but were treatment-related. Reversible salivary gland lesions (atrophy, oedema and inflammation) were observed in

all male dose groups but only in high dose females. The effects in the low dose males were classed as minimal.

The irreversible effects were increased liver weight and increased cholesterol levels in females and residual fatty hepatocellular lesions in males.

It can be concluded that repeated oral administration of the notified chemical causes liver organ toxicity and effects on coagulation resulting in internal haemorrhage.

# 9.3 Genotoxicity

## 9.3.1 Salmonella typhimurium Reverse Mutation Assay (16)

This study was conducted in accordance with the following guidelines: Standards for Toxicity Investigations (17) and The Notification on Partial Revision of Testing Methods Relating to New Chemical Substances (18).

Salmonella typhimurium strains TA 1535, TA 1537, TA 98 and TA 100 and Escherichia coli strain WP2uvrA were treated with doses up to 5000  $\mu$ g/plate in the presence or absence of metabolic activation provided by rat liver S9.

No treatment-related increase in the number of prototrophic back mutants was observed in any strain. Responses to the positive control substances 2-(2-furyl)-3-(5-nitro-2-furyl)acrylamide, sodium azide, ICR-191 and 2-aminoanthracene were as expected.

It can be concluded that the notified chemical is unlikely to be mutagenic in *Salmonella typhimurium* and *Escherichia coli*.

# 9.3.2 Chromosomal Aberrations in Chinese Hamster Ovary Cells In Vitro (19)

Chinese hamster ovary cells were treated with Z-16 in the presence or absence of metabolic activation provided by rat liver S9 for either 14 or 24 hours. Doses used were 0, 1.5, 5, 15 or 50  $\mu$ g/mL without S9 and 0, 15, 50, 150 and 500  $\mu$ g/mL with S9. Under certain conditions there were not enough cells for analysis. These were: 14 hours, -S9, 500  $\mu$ g/mL and 14 hours, -S9, 500  $\mu$ g/mL.

Control cultures exhibited a frequency of chromosomal aberrations within historical limits. The positive control substances mitomycin C (-S9), benzo(a)pyrene (+S9) and cyclophosphamide (+S9) produced the predicted increases in chromosomal aberrations.

The frequency of chromosomal aberrations was not increased by Z-16 either in the presence or absence of metabolic activation

It can be concluded that the notified chemical was not clastogenic in chinese hamster ovary cells under the conditions of the study.

# 9.3.3 Dominant Lethal Test (20)

This study appears to have been conducted using the methods of Anderson *et al.* (21) and Green *et al.* (22) but this is not specifically stated.

Sprague-Dawley male rats (15/dose) received doses of 0, 100, 300 or 1000 mg/kg/day of Z-16 for 70 days. Another group received the positive control substance triethylenemelamine at 0.05 mg/kg/day for 70 days.

As a result of mortality during the study, the highest dose group was eliminated. Two rats in the 300 mg/kg/day dose group died prior to day 70.

On day 70 each surviving male rat was co-housed with 2 virgin young adult Sprague-Dawley female rats per week for 2 consecutive weeks following which the male rats were killed and their testes and final body weights recorded.

No statistically significant reduction in fertility or increases either in pre-implantation or post-implantation loss was detected in females mated with Z-16-treated males at any of the doses evaluated.

For the positive control substance statistically significant ( $p \ge 0.01$ ) decreases in the number of live implants, increases in the number of dead implants and increases in the frequency of post-implantation loss were observed.

In can be concluded that the notified chemical did not induce dominant lethal mutations in the germ cells of the male rats under the conditions of the study.

# 9.4 Overall Assessment of Toxicological Data

The notified chemical exhibited low oral toxicity in rats, low dermal toxicity in rabbits was a slight skin and eye irritant in rabbits, a skin sensitiser in guinea-pigs and was not genotoxic as judged by induction of mutations in bacteria, chromosomal aberrations in chinese hamster ovary cells or dominant lethal mutations in the germ cells of rats. Organ toxicity was exhibited by the notified chemical during a subchronic 28-day repeated dose oral toxicity study. Irreversible liver toxicity and effects on coagulation were the main observations

On the basis of submitted data, the notified chemical would not be classified as hazardous in accordance with Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (1) in relation to Acute lethal effects (oral, dermal); Irritant effects (skin, eye) or Mutagenic effects. However, the notified chemical *would* be classified as hazardous in relation to Severe effects after repeated or prolonged exposure (oral route) and Sensitising effects (skin).

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The results ecotoxicity tests (table 2) were provided by the notifier. No precipitates or other irregularities were noted in these tests and the concentrations used were nominal. These tests were performed in accordance with Japanese Industrial Standard (for fish) and US EPA Tests Guidelines for daphnia and algal growth inhibition. The Japanese standard is similar to the OECD test guideline 203 (semi-static). All facilities used complied with OECD principles of GLP.

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Species	Test	Result
Red killifish, Oryzias latipes	48 hour acute	NOEC > 200 mg/L
Daphnia, Daphnia magna	48 hour	NOEC = 4 mg/L EC <sub>50</sub> = 12 mg/L
Alga Selenastrum capricornutum	96 hours, cell growth	EC <sub>50</sub> = 85 mg/L NOEC < 25 mg/L

#### Table 2 Ecotoxicity test results

The above results show that Z-16 is practically non-toxic to fish, moderately toxic to daphnia and slightly toxic to algae. Based on these results, chronic effects would not be expected at the estimated environmental concentrations and the lack of daphnia reproduction tests results is acceptable.

#### 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

There is expected to be 200 tonnes (maximum) of Z-16 imported as part of a formulation, which is then diluted with petroleum based oil to give a final concentration in the ready to use oil of between 0.4 and 3.2 %. This corresponds to between 6.25 ML and 56 ML of oil (assumed density of 900 g/L) containing the additive Z-16. Most of the additive is either burned with the oil during use or collected and incinerated with the waste oil. Incineration or burning of the notified chemical will only release water and oxides of carbon.

A significant amount of waste engine oil disposed of by the DIY households is not collected (19 ML). Assuming that the additive is evenly distributed across the engine oil market, then 16 tonnes of the notified chemical will be disposed of by the DIY segment of the market with the waste oil. The majority of this waste oil is disposed of with the household garbage (7 ML), buried (2.5 ML), stored (3.2 ML) or used as a weed suppressant (2.9 ML) (2). The notified chemical disposed of by landfill with the domestic garbage should slowly degrade with the oil. The same applies to the notified chemical contained in the oil that is disposed of as a weed suppressant or buried.

The remaining 3 ML of waste oil containing approximately 3 tonnes of notified chemical could disposed of by the general public by pouring it down the drain (worst case). Assuming that is evenly spread throughout year, it corresponds to 8.2 kg per day. The notified chemical is expected to be significantly diluted, estimated to be below 20 ppb (500 ML flow from city sewage works, 8 kg per day). This is nearly 2 orders of magnitude less than the NOEC for the most sensitive organism tested, daphnia. Dumping of used engine oils to stormwater is an area of concern but this practice by the general public is lessening (2).

#### 12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Exposure to undiluted Z-16 could result in slight skin and eye irritation and skin sensitisation. Possible systemic effects if the chemical enters the body include internal haemorrhage and irreversible liver damage following repeated or prolonged exposure. No acute toxic effects or genotoxic effects would be expected from exposure to Z-16. Although undiluted Z-16 was shown to be a skin sensitiser in guinea-pigs, a subsequent study demonstrated that a 40% induction dose did not produce sensitisation. Therefore, the formulation to be imported is not expected to be hazardous in terms of its potential to exhibit sensitising effects following dermal exposure.

Lubricant oil manufacture involves the use of closed systems for blending in additives and 'bottling' the resulting product. Exposure during these processes is expected to be negligible. However, there is a small possibility of exposure to the notified chemical during decanting of drums prior to blending.

It can be concluded that there is a low risk of adverse occupational health effects arising during lubricant manufacture.

The highest concentration of Z-16 in the oil added to or removed from truck engines is expected to be 3.2%. Thus, the oil is not expected to be a health hazard in terms of skin sensitisation or the effects of repeated or prolonged exposure. Exposure is possible but avoidable during oil changes and spills can be readily cleaned up. It can be concluded that there is a low risk of adverse occupational health effects for workers performing changes of oil containing Z-16.

The risk of adverse public health effects is expected to be low due to infrequent use.

#### 13. **RECOMMENDATIONS**

To minimise occupational exposure to Z-16 the following guidelines and precautions should be observed:

- if engineering controls and work practices are insufficient to reduce exposure to a safe level, then personal protective devices which conform to and are used in accordance with Australian Standards (AS) for eye protection (AS 1336, AS 1337) (23,24) and impermeable gloves (AS 2161) (25) should be worn. Overalls (AS 2919) (26) also should be worn;
- . good personal hygiene should be practised;
- work practices should be implemented to avoid spills which should be cleaned up promptly and disposed of in accordance with the recommendations contained in the MSDS and with Local and State Government regulations. During clean-up of spills, the personal protection described above should be worn;
- a copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

If the concentration of the notified chemical, Z-16, is to be imported in a formulation at a concentration that exceeds 40%, then the Director should be advised in writing.

#### 14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheets (MSDS) for Z-16 and an additive package containing it were provided in an acceptable format.

These MSDS were provided by Lubrizol International Inc as part of their notification statement. They are reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Lubrizol International Inc.

## 15. <u>REQUIREMENTS FOR SECONDARY NOTIFICATION</u>

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Z-16 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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- 21. Anderson, D, A Bateman and D McGregor, 1983, *Dominant Lethal Mutation Assays* in Dean, B J (Ed), Reports of the UKEM Sub-committee on Guidelines on Mutagenicity Testing.
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