

File No: NA/110

Date: 17/10/93

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Z-15

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Z-15

1. APPLICANT

Lubrizol Australia, 28 River St, Silverwater, NSW.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, Z-15 is considered to be non-hazardous. Therefore, the chemical name, CAS number, structural formula, exact molecular weight, spectral data and specific use have been exempted from publication in the Full Public Report and the Summary Report.

Chemical name: Z-15

Number-average molecular weight: >1000

**Maximum percentage of low
molecular weight species
(molecular weight <1000):** 9.2%

Method of detection and determination:

IR spectrum, HPLC with derivatization and fluorescence detection

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: Brown, highly viscous liquid

Pour point: 51-54°C

Density: 917.2 kg/m³

Vapour Pressure: <4.1 X 10⁻³ kPa at 25°C

Water Solubility: 1.42 mg/L at 20°C

Partition Co-efficient

(n-octanol/water) $\log P_{O/W}$: >7 (estimated)

Hydrolysis as a function of pH: No hydrolysable groups

Dissociation Constant: No dissociable groups

Flash Point: 469.6°C

Reactivity: Incompatible with
oxidising agents

Comment on physico-chemical properties:

There has been considerable confusion concerning the value and units of the water solubility. The above results have been accepted as the most likely value.

Comment on physical and chemical testing:

The octanol-buffer partition coefficient was determined in accordance with OECD Guideline 107. The submission indicates that the octanol interfered with the determination of the concentration of Z-15 in the organic layer. The experimental value quoted, $\log P > 1$ (pH 4.0, 7.0 and 9.0 at 21°C), was calculated using the original concentration of Z-15 in the octanol minus the limit of detection, divided by the limit of detection in the aqueous layer. The notifiers submit, that in their experience with similar substances, a $\log P > 7$ is expected, however no evidence to support this figure has been provided.

The substrate contains a number of basic nitrogens. A comparison with similar compounds, from the literature (1), provides the following pK_a values : 2-methylamino heptane (10.99); ethylamine (10.81); ethylenediamine (10.71); diethylamine (10.49) ; 2-aminoethanol (9.50). These data suggest for Z-15 a $pK_a \sim 10$, which indicates low dissociation.

4. PURITY OF THE CHEMICAL

Degree of purity: 99% (estimated)

Maximum content of residual monomers: None known

5. INDUSTRIAL USE

It is expected that about 70 tonnes of the notified chemical will be imported in the first year and >100 tonnes for each of the following four years.

Z-15 will be imported in 200 kg steel drums as a component of a product (LZ8137) containing mineral oil, solvents, cosolvents and corrosion inhibitors. This product, containing >40% Z-15, will be sold to blenders for blending with mineral oil and addition to bulk gasoline.

6. OCCUPATIONAL EXPOSURE

The imported product, LZ8137, containing >40% Z-15 formulated with solvents, cosolvents, oil and corrosion inhibitors, is blended with mineral oil by mechanical mixing in a closed vessel. This solution is then added to bulk gasoline using an automatic injection system while the gasoline is being transferred to road tankers. In the addition of Z-15 to the gasoline, exposure would be expected to be minimal as a result of the need to minimise exposure to gasoline. In the mixing of LZ8137 with mineral oil, exposure to Z-15 is minimised by mixing in a closed vessel and by the fact that Z-15 is highly viscous and non-volatile.

7. PUBLIC EXPOSURE

Potential public exposure to the notified chemical will occur during the handling and use of gasoline. The major route of exposure to the notified chemical will be dermal. Inhalation of the notified chemical is not likely to occur under the prescribed conditions of use due to its very low vapour pressure.

The notified chemical will be prevented from entering sewers and waterways. The notifier recommends that any spilled liquid should be collected for recycling or disposed of by incineration.

Public exposure to the notified chemical from these sources is, therefore, expected to be minimal.

8. ENVIRONMENTAL EXPOSURE

. **Release**

During blending, waste streams containing the notified polymer are confined to slops, washings and spills and contained within bunded areas for adequate treatment or disposal to prevent entry into sewers and waterways.

Z-15 is shipped as a component in a liquefied additive concentrate (>40% a.i.) to be used as a fuel additive (<0.015 % a.i.). The high molecular weight and low volatility indicate that the notified polymer should not enter the atmospheric compartment.

The compound consists of the following elements C, H, N and O. During engine use the chemical is oxidised to combustion products.

The notified polymer may be released to the environment through exhaust emissions and leakage. However, the notifier says, without supporting data, that combustion approaches 100% in the combustion chamber of the engine. Supplementary data has been supplied which indicates that in the combustion chamber the peak flame temperature ranges from 2700 - 2840°C and the exhaust gas temperature ranges from 1180 - 1200°C. These temperatures will be dependent upon a number of factors including: the engine design parameters, its state of tune, the air/fuel ratio and the type of fuel used. The notifier argues that considering the high temperatures encountered in the combustion chamber and those of the exhaust stream, the quantity of uncombusted additive is expected to be negligible. In addition, when a catalytic converter is fitted further combustion of the exhaust gases will occur.

The nature of the thermal degradation products is unknown to the notifier due to inadequate study in this area. However, the notifier suggests that at temperatures above approximately 300°C that the degradation products may be assumed to a certain monomer constituent, oligomers of it and low molecular weight amines.

The lack of data on the content and identity of combustion products and their effect on engine performance is of concern and is a major deficiency. One common additive MTBE, added at much higher levels, is known to increase NO_x levels with unknown effects on atmospheric ozone (1,2). However, even in the US these levels for detergent deposit control additives are not currently mandated and they are only required in California. There are also no current requirements to carry out these tests in Australia.

Based on the chemical composition of the notified polymer and the low concentration in fuel the company claims the product is not expected to significantly contribute to the combustion products of engine fuels.

During transportation risk of environmental exposure is limited to incidents involving an accident or leaking tanker.

Where necessary Z-15 should be disposed of by incineration.

. **Fate**

Waste polymer from the blending process will be prevented from entry into sewers and waterways. It is recommended that polymer residues be incinerated. Incineration of the polymer is unlikely to produce toxic compounds.

Hydrolysis

The structure of the notified polymer indicates that it contains no readily hydrolysable functionalities and therefore hydrolysis would not occur under environmentally relevant conditions.

Biodegradation (3)

The biodegradability of the notified polymer was assessed using the modified MITI test as per OECD Guidelines. Tests, conducted over 28 days, indicated that the polymer was not readily biodegradable under the conditions of the test and calculation from biochemical oxygen demand (BOD) data. The BOD data indicated no observable degradation after 28 days and a calculated degradation of 0%.

Bioaccumulation (4)

The bioaccumulation tests on Carp (*Cyprinus carpio*), conducted over 8 weeks, indicated that the product was not expected to have a significant potential to accumulate. The tests utilised two concentrations (each of 13 fish) and were conducted in accordance with OECD guidelines ("305C, Bioaccumulation: Degree of Bioconcentration in Fish" May 12, 1981).

Concentration	LOD	BCF
2.0 mg.L ⁻¹	5-6	14 - 37
0.2 mg.L ⁻¹	54	<u>≤</u> 54 - 123

The high molecular weight and low solubility of the major fraction of the polymer indicate that it is not expected to cross biological membranes.

Summary of Fate

The amount of polymer released to the environment through the exhaust emissions is likely to be low as the chemical is oxidised during combustion. Any emissions from the exhaust pipe can be expected to become associated with the soil compartment on the roadside. Any material deposited on the road surface would be expected to be washed into drains, when it rains, and is likely to become associated with sediments.

Whilst the majority (>90%) of the notified substance has a high number average molecular weight (NAMW >1000) a significant portion (<9.2%) falls below this level, and therefore, a potential for some of the low MW chemical to cross biological membranes exists. However, the potential for environmental contamination is limited, since, under normal conditions of use, the polymer is claimed to be fully combusted.

Studies indicate that the notified polymer is not expected to be readily biodegradable at significant rates under environmental conditions, but that it does not bioaccumulate appreciably in carp.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological data are not required under the *Industrial Chemicals (Notification and Assessment) Act, 1989, as amended* for polymers with a NAMW >1000. However, for Z-15, data on acute oral toxicity, 28-day repeated dose oral toxicity, skin and eye

irritation, bacterial reverse mutation and chromosomal aberrations in Chinese hamster ovary cells were included in the submission and are evaluated below.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Z-15

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD ₅₀ >4000 mg/kg	(5)
Skin irritation	Rabbit	Slight irritant	(6)
Eye irritation	Rabbit	Slight to moderate irritant	(7, 8)

9.1.1 Oral Toxicity (Ref No:5)

A limit test was performed using an 80% formulation of the notified chemical in diluent oil.

A single dose of the test formulation at 5000 mg/kg was administered to 5 male and 5 female Sprague-Dawley rats by gavage. All animals were killed at the termination of the study on day 15.

Diarrhoea was noted in 5 males and 1 female and decreased activity was observed in 1 male on day 2.

No animals died during the study and no abnormalities were noted during gross necropsy examination.

It is concluded that the acute oral toxicity of the notified chemical is >4000 mg/kg.

9.1.2 Skin Irritation (Ref No:6)

The test formulation containing 80% of the notified chemical in diluent oil was evaluated for potential as a primary skin irritant using 6 New Zealand white rabbits. Each rabbit was administered 0.5 ml of the test article topically to one intact and one abraded test site. Immediately following dose administration, each test site was covered with a square gauze patch held in place with tape. The trunk of each animal was occluded with a layer of plastic wrap and a stockinette sleeve

which was held in place with tape. The cuff was removed 4 hours after dose administration and the sites wiped gently with a clean gauze to remove as much non-absorbed test article as possible.

Test sites were scored at 0.5, 24 and 72 hours post-treatment. At 0.5 hours neither erythema nor oedema was observed in any rabbit. Four rabbits exhibited very slight erythema at 24 hours for both intact and abraded test sites. At 72 hours one rabbit exhibited well-defined erythema for both intact and abraded sites; the remaining 5 rabbits exhibited no erythema for the abraded sites but 2 rabbits still exhibited very slight erythema for the intact sites. As for oedema, 1 rabbit exhibited very slight oedema for an intact site at 72 hours. No oedema was exhibited by any other rabbit at any time point for either intact or abraded sites.

The results of this study indicate that OS 65919 A is a slight skin irritant.

9.1.3 Eye Irritation (Ref No:7,8)

A test formulation containing 80% of the notified chemical in diluent oil was evaluated for potential as a primary eye irritant using 6 New Zealand white rabbits. The test article (0.1 ml) was instilled into the conjunctival sac of one eye of each rabbit. The lids were held together for one second and released. Primary eye irritation was evaluated at 24, 48 and 72 hours post-treatment. The untreated contralateral eye of each animal served as a control.

Slight conjunctival redness was noted in 2 rabbits at 24 hours and in 1 rabbit at 48 hours. Slight-moderate corneal opacity was noted in 1 rabbit at 24 hours covering 1/4 or less of the area of the cornea.

In an earlier study using exactly the same procedure as above, neat Z-15 was evaluated for potential as a primary eye irritant. In this case readings were taken at 1, 2, 3, 4 and 7 days post-treatment. No effects on the cornea or iris in any of the 6 rabbits were noted. Conjunctival redness was noted in all rabbits, the maximum response being in 4 rabbits on day 1 where a diffuse crimson red was noted. In 5 of the rabbits, injected blood vessels were noted on days 2, 3 and 4 and in 2 of these rabbits also on day 7. For swelling (chemosis), the maximum response was the minimum scorable and occurred in all rabbits on

at least 1 day. Moderate discharge was noted in 5 rabbits on day 1 and 1 rabbit on day 7 with lesser responses on the other days.

Taken together, the results of the eye irritation studies indicate that Z-15 is a slight to moderate eye irritant.

9.2 Repeated Dose Toxicity (Ref No:9)

A 28-day oral toxicity study was conducted using neat Z-15 administered by gavage to Sprague-Dawley CD rats at dose levels of 100, 300 and 1000 mg/kg/day. Control animals received vehicle (corn oil) at the same dose volume as administered to the treated animals. Groups of 5 male and 5 female rats were used for the two intermediate doses. Groups of 10 male and 10 female rats were used for doses of 0 and 1000 mg/kg/day with 5 male and 5 female rats given a 14 day treatment-free recovery period from day 29 in the control and highest dose group.

All animals survived to the end of the study.

No significant physical abnormalities were observed during the treatment period and the recovery period.

Some slight differences in body weight changes were observed for males of the 1000 mg/kg/day dose group but were considered to be within normal limits.

A statistically significant increase in the total leukocyte count was noted in recovery males (1000 mg/kg/day) but no other changes in haematology values were found for any other group.

Some statistically significant increases in clinical chemistry values were found. An increase in the potassium concentration was found at termination for females in the 1000 mg/kg/day dose group. For recovery males in the 1000 mg/kg/day dose group, increases in inorganic phosphorus and serum alkaline phosphatase were found and for recovery females in the 1000 mg/kg/day dose group an increase in creatinine was observed. The increases were restricted to animals which were allowed a treatment-free recovery period following cessation of dosing.

The recovery males in the 1000 mg/kg/day dose group exhibited a statistically significant increase in adrenal to body weight and adrenal to brain weight ratios.

A treatment-related microscopic finding in the lungs of treated males and females but not in controls consisted of macrophages with coarse vacuolation of the cytoplasm. These were present in the lungs of males and females in the 1000 mg/kg/day dose group regardless of whether a two week treatment-free recovery period was allowed. Most of the treated animals exhibited a slight degree of the effect.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (10)

Z-15 was assayed for induction of prototrophic back mutants in *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and *Escherichia coli* strain WP2 in the presence or absence of metabolic activation provided by rat liver S9.

Negative controls were within acceptable limits and positive controls gave the expected responses.

Z-15 did not induce prototrophic back mutants in either of the *S. typhimurium* or *E. coli* strains in the presence or absence of S9.

9.3.2 In vitro Chromosomal Aberration Assay in CHO Cells (Ref No:11)

Z-15 was tested for the ability to induce chromosomal aberrations in Chinese hamster ovary (CHO) cells in the presence and absence of metabolic activation provided by rat liver S9.

After determination of the toxic levels of the test article, cells were treated for either 10 or 20 hours at concentrations up to 500 µg/ml. Under the conditions of the study, positive and negative controls gave the expected responses but no treatment-related statistically significant increases in the numbers of chromosomal aberrations were observed.

9.4 Overall Assessment of Toxicological Data

Z-15 is of low acute oral toxicity. Skin irritation is slight and eye irritation is slight to moderate. It is not genotoxic as judged by the bacterial reverse mutation assay and induction of chromosomal aberrations in CHO cells.

The results of the 28-day repeated dose study suggest that some changes were observed in the haematology and clinical biochemistry values, but these were not toxicologically significant. However, a dose-related increase in cytoplasmic vacuolation in alveolar macrophages was observed. This was thought to be due to a interference with enzymatic removal of phospholipids or in macrophage clearance and may suggest that adverse respiratory effects could result from repeated ingestion.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Acute toxicity to orange-red killifish (*Oryzias latipes*) was determined in accordance with OECD guidelines to reveal a 48 h LC₅₀ of ≥ 300 mg.L⁻¹ using a semi static system (renewal of test water every 8 - 16 hours). This test was conducted jointly with the bioaccumulation test which stated that the solubility of the notified substance was 11 mg.L⁻¹. The high concentration of notified substance in the test solution was achieved by first dissolving the notified substance and dispersant in tetrahydrofuran. Deionised water was then added before evaporating off the tetrahydrofuran.

The literature indicates that quaternary amines may exhibit aquatic toxicity (12), with green algae about 6 times more sensitive than fish (13). The literature suggests that this class of polymer is surface active, reacting with the biological membranes. As MW drops below 1000 some systemic toxicity has been noted. Toxicity would only be of concern if very high levels of uncombusted polymer are emitted.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Emissions during engine use are unlikely to present a hazard to the environment as the amount of intact polymer being lost is likely to be very low due to the oxidation of the polymer during combustion.

The product is only imported as part of an additive package (>40% a.i.) which is blended with fuels at refineries. Spillages at the site of reformulation will be collected and disposed of by incineration. The most likely pathway for the notified substance to enter the aquatic compartment is as a result of accidental spillage of the reformulated fuel. The concentration of the

notified substance in fuel is 141 ppm, which is of the same order of magnitude as the acute toxicity to aquatic species. This does not include the significant levels of dilution which would occur upon entry to and movement through the aquatic compartment.

Inclusion of Z-15 additive in fuel is not expected to increase the hazard associated with its use compared to that of the untreated product. However, it remains unclear whether any effect on emission performance may be expected.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The toxicological profile of Z-15 suggests it would be of low acute toxicity following ingestion although ingestion over a long period may have adverse effects.

Short term exposure of the skin to Z-15 may result in slight irritation whereas exposure of the eye may result in slight to moderate irritation. No genotoxic effects are expected.

The highly viscous and non-volatile nature of Z-15 minimises the risk of inhalational exposure and makes spillage less likely.

It is expected that exposure to Z-15 during the addition and blending of LZ8137 with mineral oil in a closed vessel would be low. Also, the controls required to reduce exposure to the solvents contained in LZ8137 namely, xylene, 2-ethylhexanol and ethylbenzene, would be expected to minimise exposure to Z-15 itself. Exposure to Z-15 during addition of the resulting solution to gasoline would be expected to be minimal as a result of the controls employed to minimise exposure to the gasoline itself.

Public exposure to the notified chemical is anticipated as it is to be marketed as an additive in gasoline sold to the public. However, it is anticipated that the general public will only be exposed to the additive at low levels through accidental exposure to gasoline as it is pumped into the vehicle. In view of the low toxicity of the notified chemical, the hazard to the public would be expected to be minimal from this aspect of the chemical use.

13. RECOMMENDATIONS

To minimise occupational exposure (and public/environmental if recommendations have been made by these agencies) to Z-15 the following guidelines and precautions should be observed:

- . if engineering controls and work practices are insufficient to significantly reduce exposure to Z-15 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) (14,15), impermeable gloves (AS 2161) (16) and protective clothing (AS 3765.1, 3765.2) (17,18) should be worn;
- . good work practices should be implemented to avoid spillages and splashing;
- . good housekeeping and maintenance should be practised. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal in accordance with local or State regulations;
- . storage should be in robust sealed containers;
- . good personal hygiene should be observed; and
- . a copy of the Material Safety Data Sheet should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for LZ8137 containing the notified chemical (Attachment 1) was provided in Worksafe Australia format (Ref No:19). This MSDS was provided by Lubrizol Australia 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 Lubrizol Australia.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989, as amended* (the Act), secondary notification of Z-15 shall

be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. The lack of data on the content and identity of combustion products and their effect on engine performance is of concern and is a major deficiency. These tests may be required with future submissions.

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