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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Z-12

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Z-12

1. APPLICANT

Lubrizol International Inc of 28 River St, Silverwater, NSW 2141 has submitted a standard notification statement accompanying their application for assessment of Z-12.

2. IDENTITY OF THE CHEMICAL

Z-12 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae and spectral data have been exempted from publication in the Full Public Report and the Summary Report

Trade name: Z-12

Molecular weight: ca. 2000 - 2100

Methods of detection and determination:

Analysis by inductive-coupled plasma emission spectroscopy, IR and NMR.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Red/brown viscous liquid
Melting Point:	-37.8 to -36.1°C
Boiling Point:	Does not boil under normal circumstances; decomposes at 388°C
Relative Density:	1.0406 at 20.5°C
Vapour Pressure:	2.5×10^{-4} to 2.3×10^{-3} Pa
Flash Point:	> 224°C
Flammability Limits:	Not performed (It has a low vapour pressure and a relatively high closed cup flash point. It is not pyrophoric nor reactive towards water.)
Auto-ignition Temperature:	421 ± 0.8°C

Explosive Properties: None

Reactivity/Stability: It is not an oxidising agent. Not stable in water.

Comments on physico-chemical properties

Water solubility, hydrolysis, partition co-efficient, adsorption/desorption and dissociation constant could not be determined because of the chemical's instability in water. The notifier states that instability was determined in an "in-house", non-standard experiment. The chemical was dissolved in diethyl ether and shaken with water, then the organic and aqueous phases separated. Most of the mass of the material remained in the organic phase (as weighed after evaporation of diethyl ether. The rate of decomposition was not determined, although the notifier claims, and the above indicates, that it is rapid.

4. PURITY OF THE CHEMICAL

Degree of purity: Not known

Toxic impurities: None

Non-hazardous impurity: Not known

Additives: None

5. INDUSTRIAL USE

The notified chemical will be used as a friction modifier and a pressure/antiwear agent in car motor oils particularly high performance synthetic motor oils. Virtually 100% of sales of the car motor oil blended with the notified chemical will initially be sold to car racing teams and new car dealers.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported into Australia as an ingredient in the product LZ 8897B at a concentration of 1-10%, which will be shipped by isotainer and transported to the processing plant most likely by rail.

The import volumes are estimated to be a maximum of 1.1 tonnes per year for the first five years.

At the blending facility the formulation containing the notified chemical will be decanted by pumping into an open trough from which it is pumped into a closed blend tank where it is mixed with oil and possibly other additives. Blend sizes will range from 1000 to 2000 kg. Following blending for about 3 hours involving two operators the blend is drummed off into 1, 5, 10, 60 and 205 L containers. The drumming process involves 3 operators for about 2 hours. There is expected to be 58 blends per year.

The final concentration of the notified chemical in motor oils is about 0.16 to 0.18 %w/w. The motor oils are expected to be used by motor car racing teams and new car dealerships for oil changes.

7. PUBLIC EXPOSURE

The oil containing the notified chemical will not be sold to the general public for do-it-yourself oil changes. Public exposure to the notified chemical from its use in motor oils is expected to be minimal.

No public exposure to the notified chemical is expected during transport and blending processes other than in the case of accidental spillage. The exposure will be minimal if the spills are contained and cleaned up by the recommended practices as outlined in the MSDS.

Disposal of the used oil is expected to be by incineration.

8. ENVIRONMENTAL EXPOSURE

. Release

The notified chemical, as part of a lubricant concentrate, will be added to oils to give friction modifying and high pressure/antiwear properties at a number of processing sites. The lubricant concentrate, LZ 8897B, will be blended in a closed tank, with the empty concentrate containers then sent to a reconditioning facility. The notifier expects any Z-12 residue in empty concentrate containers to be minimal and readily removed at the reconditioning facility. Any residue left in the blending tank and associated equipment would be incorporated into subsequent batches, as equipment is usually used for similar materials. If cleaning with mineral oil does occur, this would be used in another blend. The concentration of the notified chemical in blended products is expected to be 0.16-0.8% (w/w), and packaged into 1, 5, 10, 60, and 205 L containers. Any release is expected to occur from accidental spillage, which should be adsorbed onto inert material and then disposed of according to relevant government regulations.

. Fate

The notified chemical will be used in premium, high performance automotive oils, particularly aimed at motor car racing teams and new car dealerships.

A minor component will be released to the environment from spills and leaks - 0.5% of lubricants sold for cars and trucks are expected to be released to the environment in this fashion (1). Such leaks would be widely dispersed and rapidly decompose to a naturally occurring phosphate ester and borate when it came into contact with water.

The notifier estimates that 30% of the expected volume to be used (ie 30% x 1 tonne = 300 kg) will be unaccounted for, based on European figures for the fate of crankshaft oils (1).

- *biodegradation*

The ability of the notified chemical to biodegrade was assessed using OECD Test guideline 301B (Modified Sturm Test). Carbon dioxide evolution was measured. The notified chemical was tested at two concentrations of 10 and 20 mg/L. It gave 75% and 24% conversion to CO_2, respectively, after 10 d, and 91% and 39% conversion to CO_2, respectively, after 28 d. It is suggested that the lower production of CO_2 at the higher test concentration was likely due to its low (aqueous) solubility, therefore limiting its bioavailability. It is concluded that the notified chemical can be classed as readily biodegradable. It is generally recognised that the major chemical component used to manufacture the notified chemical is biodegradable.

- *bioaccumulation*

The bioaccumulation potential of the notified chemical was claimed to be low by the notifier, because of its ready biodegradability. There is literature support for this contention (2) in that its ready biodegradation, as well as its instability in water and low water solubility (<<0.002 mol/m^3), is likely to limit bioaccumulation.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Z-12

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

9.1.1 Oral Toxicity (3)

Ten SD rats (5/sex) were administered 5000 mg/kg Z-12 suspended in corn oil by a single oral gavage and observed for 14 days prior to necropsy. No deaths occurred. Decreased activity was observed in 5 males and 4 females on the first day after dosing; otherwise the animals appeared normal during the observation period. No gross lesions were found at necropsy. The oral LD_{50} of Z-12 was greater than 5000 mg/kg.

9.1.2 Dermal Toxicity (4)

Young adult NZW rabbits (5/sex) were dermally treated with 2000 mg/kg Z-12 on intact (3 male and 2 female) or abraded skin (2 male and 3 female) under occlusive dressing for 24 hours. The observation period was 14 days. No deaths occurred. Erythema was seen at the application site, but no signs of systemic toxicity were observed. No gross lesions were found at necropsy. The dermal LD_{50} of Z-12 in rabbits was greater than 2000 mg/kg.

9.1.3 Inhalation Toxicity

No studies were submitted.

9.1.4 Skin Irritation (5)

Six young adult NZW rabbits (3/sex) were dermally treated with 0.5 ml of Z-12 on the intact skin under a gauze patch for 4 h. The animals were examined at 24 and 72 h after initiation of treatment. The irritation was scored according to the Draize method.

Very slight erythema and oedema were observed in 4 animals at 24 h. At 72 h, very slight erythema was seen in 2 animals and well-defined erythema in one animal, and no oedema was present in any animals. The test material was a slight skin irritant in rabbits.

9.1.5 Eye Irritation (6)

Six young adult NZW rabbits (3/sex) were treated with 0.1 mL of Z-12 by instillation into one eye of each animal. The eyes were examined at 24, 48 and 72 h after instillation. The cornea and iris were not affected by the treatment. At 24 h, 3 animals showed slight redness of the conjunctivae and the other 3 animals showed diffuse redness. Slight conjunctival swelling was seen in all the animals. Ocular discharge was observed in three rabbits. At 48 h, 5 animals showed slight redness of the conjunctivae, and 4 animals had slight conjunctival swelling. By 72 h, two animals had slight redness and swelling of the conjunctivae. The test material was a slight eye irritant in rabbits.

9.1.6 Skin Sensitisation (7)

The skin sensitisation potential of Z-12 was studied in Hartley albino guinea pigs using a modified Buehler method.

In the primary irritation test, the test substance was diluted to 50, 25, 10 and 5 %w/v in heavy mineral oil. An aliquot of 0.4 ml of the undiluted Z-12, all diluted solutions and heavy mineral oil were applied to the skin of 16 guinea pigs (8/sex) for 6 h using a 25 mm Hill Top Chamber. The animals were examined at 24 and 48 h after treatment. The test material induced very slight erythema.

After the primary irritation test, 10 guinea pigs (5/sex) were induced with the undiluted test material applied as described above in the primary irritation test once a week for 3 weeks. Two naive control groups (5/sex/group) remained untreated during the induction period. Two weeks after the last induction exposure, the test group and control group I were challenged with 25 %w/v of the test material in heavy mineral oil. One week after the initial challenge, the test animals were rechallenged with 5 %w/w test material in heavy mineral oil, and the control group II was also challenged with the same dilution of test material. The skin reactions were examined at 24 and 48 h after induction or challenge treatment.

Very slight erythema was observed after the induction exposures. After challenge or rechallenge exposure, very slight to slight erythema was seen in all the naive control and test animals. Positive reactions (moderate to severe erythema) were observed

in a positive control group with a known dermal sensitiser, dinitrochlorobenzene. Z-12 was not a skin sensitiser in guinea pigs.

9.2 Repeated Dose Toxicity (8)

SD rats (5/sex/group) were orally administered 0, 100, 300 or 1000 mg/kg/day Z-12 in corn oil for 28 days by gavage. Two additional groups were similarly dosed with 0 and 1000 mg/kg/day, respectively, and recovered for two weeks after cessation of administration before being killed.

No treatment-related deaths or clinical signs were observed in the control and test animals. There were no changes in body weight gain, feed consumption, urinalysis, haematology or clinical chemistry. Organ weights were not affected by treatment. No treatment-related macroscopic or microscopic changes were detected.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium and Escherichia coli Reverse Mutation Assays (9)

Salmonella typhimurium TA98, TA100, TA1535 and TA1537, and *Escherichia coli* WP2 were cultured with 0.005 - 1.5 mg/plate of Z-12 dissolved in tetrahydrofuran with and without metabolic activation using rat liver S9. Precipitation was seen at the highest concentration. Negative (solvent) and positive controls were run concurrently. All dose levels were plated in triplicate. In the positive controls, 2-aminoanthracene was used in the presence of S9 in all the strains and in the absence of S9, 2-nitrofluorene was used in strain T98, *N*-ethyl-*N*'-nitro-*N*-nitrosoguanidine in strains TA100 and WP2, sodium azide in strain TA1535, and 9-aminoacridine in strain TA1537.

The number of revertants was comparable between the solvent control and test groups. The positive controls produced marked increases in revertant counts in all the test strains. Under the condition of the assay, Z-12 was not mutagenic in the *Salmonella typhimurium* and *Escherichia coli* reverse mutation assays.

9.3.2 Chromosomal Aberrations in Chinese Hamster Ovary (CHO) Cells (10)

CHO cell cultures were treated with Z-12 dissolved in tetrahydrofuran for 10 or 20 h before cell harvest. In the presence of rat liver S9, the concentrations of the test material were 1.5 - 505 μg/ml in the 10-h harvest group and 1.4 - 457 μg/ml in the 20-h harvest group. In the absence of rat liver S9, the concentrations were 1.5 - 2470 μg/ml in the 10-h harvest group and 1.5 - 2520 μg/ml in the 20-h harvest. The test was conducted in duplicate. Tetrahydrofuran was used as a negative (solvent) control, and mitomycin C and benzo(a)pyrene were used as positive controls.

No increases in the incidence of chromosomal aberrations, including or excluding gaps, were produced by Z-12. Significant increases in chromosomal aberrations were observed in the positive controls. Z-12 was not clastogenic in the CHO *in vitro* chromosomal aberration assay.

9.4 Overall Assessment of Toxicological Data

Based on the toxicity studies provided, the notified chemical was of low acute oral toxicity in rats and low dermal toxicity in rabbits. It was a slight skin and eye irritant in rabbits, but was not a skin sensitiser in guinea pigs. Repeated administration of Z-12 at up to 1000 mg/kg/day for 28 days did not produce any noticeable toxic effects in rats. It was not mutagenic in the Ames mutation assay and did not cause chromosomal aberrations in CHO cells *in vitro*.

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* (11) in relation to Acute lethal effects (oral, dermal) ; Irritant effects (skin, eye); Sensitising effects (skin); Severe effects after repeated or prolonged exposure (oral route) or Mutagenic effects.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicity studies were conducted using Z-12 according to OECD guidelines (table 2).

The report for the fish test indicates that after preliminary testing (5 test concentrations, control without carrier, control with carrier, 10 fish per group), 20 fish were used in each of two test concentrations (500 and 1000 mg/L), as well as the two controls. The carrier used was an acetone/Tween 80 (50/50, w/w) mixture at 10% of test substance concentration. Test solutions were stirred 5 times every 24 h. Measured test concentrations were based on the concentration of boron in the test solution, and did not change markedly over time. The test solutions were made cloudy by the test substance, and as well there was some deposit on the bottom of the test tank, and flocculation and foam (from vigorous aeration) on the surface of the water. Fish showed abnormal swimming behaviour (eg lethargy) at both test concentrations after 2 h of the start of the study, and respiration problems (abnormal red brachial colouration) at the highest test concentration; only one death was observed at this concentration. The LC_{50} of Z-12 is therefore > 1400 mg/L (measured concentration), although the NOEC is < 700 mg/L.

The water flea test was performed in a similar fashion to the fish test, with minimal differences, except that the actual test used 7 test concentrations (8 were used in the preliminary test) of 0.001, 0.01, 1, 10, 100, and 1000 mg/L and two controls as described previously. Cloudiness and some deposition on the bottom of the test tank, were noted in the two highest concentrations as soon as 3 h after the start of the study. Only one water flea was found to be immobile at the end of the test, and this was observed in the highest test concentration. The EC_{50} of Z-12 is therefore > 1140 mg/L, and the NOEC is 103 mg/L (measured concentrations, results based on survival/immobility).

The algal test was performed using the water accommodated fraction of the test substance (test substance stirred for 20 h, solution allowed to settle and aqueous phase then used), after preliminary experiments indicated no effects at nominal concentrations of up to 100 mg/L. Measured concentrations (based on boron concentration) at 0 and 96 h after the start of the test varied from 57-95% and 45-

92% of the nominal test concentrations, respectively. The test report gives: (i) changes in mixing ratios due to viscosity of the test substance, and (ii) sampling a water accommodated fraction of a "nonwater-soluble test material" leading to a non-homogeneous mixture, as the cause of this variability. The test substance rapidly decomposes and components of the algal culture medium might chelate one of the decomposition products in a non-uniform fashion and contribute to the observed variability. The E_BC_{50} (cell number as endpoint) and E_RC_{50} (growth rate as end point) were both determined to be >580 mg/L (mean measured concentration). Some significant algae-static effect was observed in the first 48 h of the test, although this effect did not persist.

The notified chemical did not inhibit activated sludge in the metabolism of the reference compound, sodium benzoate (at 20 mg/L) when present at a concentration of 10 mg/L (Table 2).

Table 2 Ecotoxicity test results

Species	**Test**	**Result** (mg/L)[a]
Zebra fish (*Brachydanio rerio*)	96 h acute, static-renewal	LC_{50} > 1000 (*1400*)[b,c]
Water Flea (*Daphnia magna*)	48 h acute, static-renewal	EC_{50} >1000 (*1140*)[d,c]
Algae (*Selenastrum capricornutum*)	96 h	E_BC_{50} > 1000 (*580*) E_RC_{50} > 1000 (*580*)[e]
Activated sludge from municipal sewage treatment	28 d, inhibition assay	57 & 85% biodegradation at 10 & 28 d, respectively[f]

a. Test substance rapidly decomposes in water to lecithin and boric acid. Actual test concentrations, given in brackets, are based on measured boron concentrations; b. Limit of detection was 3.7 mg/L, maximum concentration in controls < limit of detection; c. carrier used - see text; d. Limit of detection was 3.7 mg/L, maximum concentration in controls was 6.6 mg/L, e. water accommodated fraction used with variability in measured concentrations - see text for details; f. test performed using sodium benzoate at 20 mg/L and Z-12 at 10 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical will be used as an additive for automotive oils. The main environmental exposure of oils, in general, results from inappropriate disposal of oil from do-it-yourself oil changes (12)[1]. None of the oil containing the notified chemical is expected to be sold to the general public for do-it-yourself oil changes. The notified chemical is therefore expected to share the fate of the oil, with most spent oil being combusted if used for fuel or recycled.

[1] No figures are available for how much automotive oil was collected for re-use, but it is estimated that about 35% of all oil sold is not collected and possibly disposed of in an inappropriate manner after do-it-yourself oil changes. This agrees closely with the European figure of 30%.

If all of the unaccounted oil was disposed of in an inappropriate manner, then a worst case scenario would be if all of this uncollected oil was dumped into a sewer in some country centre. This, however, would give a concentration of only about 200 µg/L per day[2]. For a major city, the amount would only be about 2 µg/L per day. However, with its use Australia wide, and with good industrial and public practice, as well as its likely market being restricted to car racing teams and new car dealerships, significant aquatic exposure to the chemical is not expected.

Tests showed that the chemical is expected to rapidly decompose and readily biodegrade, and be non-toxic to aquatic organisms up to the limit of its solubility. Decomposition products are a phosphate ester and borate, both of which are naturally occurring and widespread in the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

On the basis of studies in animals the notified chemical would not be expected to exhibit toxic effects on acute, repeated or prolonged exposure, is likely to be, at most, a slight skin and eye irritant, is not likely to be a skin sensitiser and is not likely to be genotoxic.

Exposure to the notified chemical is expected to be minimal during blending into car motor oils on the basis that it is at a maximum concentration of 10% weight in the imported formulation and is largely in an enclosed system at the facility where blending occurs. Some exposure is possible during decanting of the imported formulation from drums into an open trough prior to pumping into an enclosed mix tank. However, since a maximum of 80 drums per year are processed, exposure is expected to be low.

Exposure to the notified chemical during oil changes by car racing teams and in new car dealerships is expected to be minimal in view of the fact that its concentration in motor oil is about 0.16 to 0.18 %w/w.

Given the toxicity profile of the notified chemical and the likely low exposure, the risk of adverse occupational and public health effects is expected to be minimal during transport, storage, use and disposal.

13. RECOMMENDATIONS

To minimise occupational exposure to Z-12 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 or Australian/ New Zealand Standards (AS or AS/NZS) for eye protection (AS 1336, AS/NZS 1337) (13,14) and impermeable gloves (AS 2161) (15) should be worn. Overalls conforming to

[2] Given 385 kg of the oil additive would not be collected (i.e. 35% x 1100 kg), a daily average would be about 1 kg/d (i.e. 385 kg/365 d). The dilution at a rural town could reasonably be expected to be about 5 ML, while for a major city, say Melbourne, it would be 500 ML. This would give final concentrations of the oil additive of 200 µg/L per day and 2 µg/L per day, respectively.

AS 2919 (16) and protective footwear conforming to AS/NZS 2210 (17) also should be worn;

. generation of mists during blending should be avoided and local exhaust ventilation should be used if mist generation is likely;

. 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 Local or 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.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet for Z-12 was provided in an acceptable format.

This MSDS was provided by Lubrizol International Inc 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 International Inc.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Z-12 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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17. Standards Australia, Standards New Zealand 1994, *Australian/ New Zealand Standard 2210 - 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications,* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.