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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Z-34

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FULL PUBLIC REPORT**Z-34****1. APPLICANT**

Lubrizol International Inc of 28 River Street SILVERWATER NSW 2128 (ACN 002 747 944) has submitted a notification statement in support of their application for an assessment certificate for the synthetic polymer of low concern (PLC) Z-34.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the polymer composition, impurities and import volumes have been exempted from publication in the Full Public Report.

Marketing names: Z-34

Other names: OS142485
Lubrizol 0805.2 (10% Z-34)

3. POLYMER COMPOSITION AND PURITY

Details of the polymer composition have been exempted from publication in the Full Public Report.

4. PLC JUSTIFICATION

The notified polymer meets the PLC criteria.

5. PHYSICAL AND CHEMICAL PROPERTIES

Some data of the physical and chemical properties were generated from Lubrizol 0805.2, which contains 10% Z-34, 22% diethylene glycol (CAS No. 111-46-6) and 68% water.

Property	Result	Comments
Appearance	Z-34: odourless white crystalline solid;	

	Lubrizol 0805.2: light yellow viscous liquid.	
Melting point	Not determined.	Variation applied, liquid at room temperature.
Density	Z-34: 900 kg/m ³ at 15.6°C; Lubrizol 0805.2: 1 065 kg/m ³ at 15.6°C.	
Water solubility	Z-34: 447-469 g/L at 20°C.	
Particle size	Not determined.	Variation applied.
Flammability	Not determined.	Variation applied.
Autoignition temperature	Not determined.	Variation applied.
Explosive properties	Not determined.	Not expected to have explosive properties.
Stability/reactivity	Stable at under normal conditions.	Not an oxidizer.

5.1 Comments on physical and chemical properties

The specific gravity of pure solid Z-34 was not determined. The manufactured material 0805.2 that contains Z-34 was measured to have a specific gravity of 1.065 at 15.6°C.

The water solubility of the notified polymer was determined in accordance with OECD Test Guideline 105, using the Flask Method (SafePharm, 2001). The solubility of the polymer was determined to be 447-469 g/L and the polymer can be regarded as readily soluble.

The hydrolysis potential of the notified chemical was not determined. However, the polymer contains amide functionalities, but these would not be expected to significantly hydrolyse under environmental conditions (pH 4-9).

The partition coefficient of the notified polymer was not determined but the high water solubility of the polymer indicates that it would be expected to preferentially partition into the aqueous phase.

The adsorption/desorption behaviour of the notified polymer was not determined. Again, the high water solubility of the polymer indicates that it is likely to be mobile in soils.

The notified polymer contains a strongly acidic sulphonyl group which would readily dissociate under environmental conditions (pH 4-9).

6. USE, VOLUME AND FORMULATION

Use:

Metalworking additive.

Manufacture/Import volume:

Up to 50 tonnes of the notified polymer will be imported annually in the first 5 years.

Formulation details:

Lubrizol 0805.2 containing 10% Z-34, 22% diethylene glycol and 68% water will be imported in sealed 55 gallon (208 L) plastic drums. It will not be further formulated in Australia but will be distributed as a ready-to-use metalworking additive. At machinery plants, Lubrizol 0805.2 will be added directly to metal working fluid reservoirs at 500 ppm, for end use.

7. OCCUPATIONAL EXPOSURE

The number of workers in each category and the duration and frequency of exposure was not provided.

Exposure route	Exposure details	Controls indicated by notifier
<i>End use</i>		
<i>Machinery workers</i>		
Dermal, ocular	Measuring, adding, mixing and applying.	Nitrile or neoprene gloves, safety glasses and long sleeve shirt.
<i>Transport and storage</i>		
<i>Waterfront workers, driver, and storage workers</i>		
Dermal, ocular	Contact only likely in the event of a spill.	Not specified.
<i>Disposal</i>		
<i>Reconditioning facility workers</i>		
Dermal, ocular	Opening containers and washing them with water.	Nitrile or neoprene gloves, safety glasses and long sleeve shirt.

8. PUBLIC EXPOSURE

The notified polymer and the product containing the notified polymer are not available for sale to the general public. The product containing the notified polymer will be used as a

additive in metalworking fluid. Since the product containing the notified polymer is only used for industrial purposes, the potential for public exposure to the notified polymer is likely to be negligible.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

Release to the environment prior to end use is expected to occur only in the unlikely event of an accident during transport or an accidental leak. The additive packages containing the notified polymer will be delivered to the metalworking facilities as an aqueous solution in 55 gallon plastic drums. It is anticipated that there will be minimal release of the notified chemical during transfer from the storage containers to the metalworking fluid reservoir.

The notifier has stated that used plastic 55 gallon drums containing notified polymer residues would be sent to a reconditioning facility where residual matter will be removed by washing with water. Residual product is anticipated to be no more than 2%. Therefore, less than 1 tonne of the polymer will be discharged to the sewer system from this route.

The notifier has stated that, due to its high molecular weight, the notified polymer is not present in the mist generated during the metalworking phase and that it will drip from the cutting edge and be recaptured through a catching mechanism. These wastes will typically be treated similarly to engine oil wastes, and will be recycled or incinerated as fuel. However, in spite of the good shear stability of the polymer and hence greater reuse potential, it is likely that old metalworking fluids will be totally removed on a periodic basis. This waste is likely to be removed by liquid waste contractors and would presumably be disposed of through accepted methods such as incineration or biological treatment prior to discharge of the treated effluent to sewer. During these operations, solid material (eg. fine metal cuttings) which have accumulated in the systems would also be removed and may be placed into landfill, or be inappropriately disposed of to the sewer. It is likely that, while large factories will periodically have their inventory of old cutting fluid removed in this manner, this may not be the case for smaller establishments. In the case of smaller factories and metal working shops (eg. motor garages) it is assumed that much of the old fluid would be disposed of to the sewer, or possibly be allowed to spill onto the ground. If it is assumed that up to 50 tonnes of the new chemical will be used each year within Australia, and 50% of this is will be used by small factories, it is possible that up to 25 tonnes per annum of the new chemical may be released to the sewer without pretreatment, or be disposed of into land.

During use of the cutting fluids some will be lost through splashes and spills. In addition, it is likely that a portion of the polymer will be present in the mist and will eventually precipitate as it is in aerosol form, rather than vapour. While this is likely to be contained within bunds at large establishments (then sent to sewer), at smaller shops the spilt material would most likely be absorbed with metal dust and disposed of to landfill with everyday waste. If it is assumed that overall losses due to splashes and aerosols amount to 20% of polymer used annually, and that 50% of this is disposed of to sewer and 50% to landfill, then an additional 5 tonnes may reach the sewer each year and 5 tonnes may go to landfill.

Overall, up to 30 tonnes of the notified polymer per annum may be disposed to landfill and up to 31 tonnes per annum may be disposed of to sewer, depending on local waste disposal practices.

9.2. Fate

The notified polymer, will share the fate of metalworking fluids into which it has been incorporated. The notifier has indicated that metalworking fluid residues will be typically be treated as waste engine oils and are likely to be recycled or incinerated. However, it is likely that, especially, smaller users may inappropriately dispose of some of the polymer. Up to 30 tonnes of the polymer generated from the metalworking process will go to landfill or be incinerated while up to 30 tonnes will go to sewer. In addition, waste oil containing the notified polymer residues (up to 1 tonne) washed from used drums will be disposed of to the sewerage system.

In the case of release to landfill, the anticipated low K_{OC} (see physico-chemical properties) indicates that the material would be mobile in landfill. Incineration of the waste polymer would destroy the substance with evolution of water vapour and oxides of carbon, nitrogen and sulphur, together with production of sodium compounds that would be assimilated with the ash. If disposed of to the sewer, the high water solubility of the polymer indicates that it will partition into the aqueous component.

Bioaccumulation of the notified polymer is unlikely due to its high water solubility and high molecular weight (Connell, 1990).

10. EVALUATION OF HEALTH EFFECTS DATA

10.1 Toxicological studies

The notifier provided a report of Ames test on the notified polymer (OS142485) and two skin and eye irritation studies on OS135262 containing 10% Z-34, 45% propylene glycol and 45% water.

10.1.1 Skin Irritation (WIL, 1997a)

<i>Test material:</i>	OS135262A
<i>Species/strain:</i>	Rabbit/New Zealand White
<i>Number/sex of animals:</i>	3/sex
<i>Observation period:</i>	Up to 7 days
<i>Method of administration:</i>	A dermal dose of 0.5 mL was applied under a semi-occlusive dressing to the clipped intact skin of each rabbit

for 4 hours.

Test method: OECD TG 404

Draize scores:

<i>Time after treatment</i>	<i>Animal #</i>					
	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>	<i>6</i>
<i>Erythema</i>						
0.5-1 hr	^a 0	1	0	1	0	0
24 hrs	0	0	1	1	0	0
48 hrs	0	0	0	0	0	0
72 hrs	^d 0	0	0	^d 1	0	0
4 days	^d 0	-	-	1	-	-
5 days	0	-	-	1	-	-
6 days	-	-	-	1	-	-
7 days	-	-	-	0	-	-

Oedema

Zero scores were recorded for oedema effects in all animals at all time points

^a see Attachment 1 for Draize scales

^d desquamation

Comment: None.

Result: The test material was slightly irritating to the skin of rabbits.

10.1.2 Eye Irritation (WIL, 1997b)

Test material: OS135262

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 6 males

Observation period: Up to 7 days

Method of administration: A dose of 0.1 mL was applied to conjunctival sac of the right eye. The untreated left eye served as control.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

<i>Animal</i>	<i>Time after instillation</i>																	
	<i>1 hour</i>			<i>1 day</i>			<i>2 days</i>			<i>3 days</i>			<i>4 days</i>			<i>7 days</i>		
<i>Cornea</i>	Zero scores were recorded for cornea effects in all animals at all time points																	
<i>Iris</i>	Zero scores were recorded for iridial effects in all animals at all time points																	
<i>Conjunctiva</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>
1	1	1	0	1	1	0	1	1	0	0	0	0	-	-	-	-	-	-
2	1	1	0	1	0	0	0	0	0	0	0	0	-	-	-	-	-	-
3	1	1	0	1	0	0	1	0	0	0	0	0	-	-	-	-	-	-
4	1	0	0	0	0	0	0	0	0	0	0	0	-	-	-	-	-	-
5	1	1	0	1	1	0	1	0	0	0	0	0	-	-	-	-	-	-
6	1	1	0	1	0	0	1	0	0	1	0	0	1	0	0	0	0	0

¹ see Attachment 1 for Draize scales

r = redness c = chemosis d = discharge

Comment: Fluorescein examination results showed no abnormalities after treatment.

Result: The test material was slightly irritating to the eyes of rabbits.

10.2 Genotoxicity

10.2.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Safepharma, 1999)

Test material: Z-34

Strains: *Salmonella typhimurium* TA1535, TA1537, TA98, TA100 and *Escherichia coli* WP2uvrA.

Metabolic activation: Liver fraction (S9 mix) from rats pretreated with Aroclor 1254.

Concentration range: Triplicate plates were prepared for each bacterial strain and dose level, in both the presence and the absence of S9-mix. Distilled water was used as the vehicle.

0, 50, 150, 500, 1 500 and 5 000 µg/plate in all strains.

Positive controls:

(When with S9 mix)
Benzo(a)pyrene (BP) for TA98, and
2-Aminoanthracene (2AA) for the remaining strains.

(When without S9 mix)
N-ethyl-N'-nitrosoguanidine (ENNG) for TA100, TA 1535
and WP2uvrA,
9-Aminoacridine (9AA) for TA1537, and
4-Nitroquinoline-1-oxide (4NQO) for TA98.

Test method: OECD TG 471

Comment: No cytotoxicity was observed to any the strains of bacteria used except in TA98 at 5 000 µg/plate with and without S9-mix in the range finding study.

Under the conditions of the study, the test material caused no substantial increases in revertant colony numbers over control counts at any concentration in either the presence or absence of the rat liver microsomal enzymes.

All positive controls responded appropriately.

Result: The notified chemical was non mutagenic under the conditions of the test

10.3 Overall Assessment of Toxicological Data

The health hazards of the constituents and hazardous impurities, additives and adjuvants for Z-34 are tabulated below.

Chemical	Health hazards	Regulatory controls
Constituents	<i>None.</i>	<i>None.</i>
Hazardous impurities	<i>None.</i>	<i>None.</i>
Additives/adjuvants	<i>None.</i>	<i>None.</i>

The toxicity studies showed that a product, OS135262 containing 10% the notified polymer was a slight skin and eye irritant in rabbits. The Ames study report on the notified polymer indicated that it was not mutagenic in bacterial strains tested. The notified polymer cannot be classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b) for the endpoints tested.

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

No ecotoxicological data were provided.

12. ENVIRONMENTAL RISK ASSESSMENT

The environmental hazard from the notified polymer is considered to be low provided that the material is used as indicated, and that disposal of waste metalworking fluid follows approved practices. Apart from transport accidents or accidental spills or leaks, minimal release of the notified polymer is expected as a result of transfer to metalworking fluid reservoirs. The notifier has indicated that spent fluid will be treated similarly to waste engine oils and will be recycled or incinerated. However, inappropriate disposal by smaller operators could mean that up to 30 tonnes of the polymer may be disposed to landfill and other land, and up to 31 tonnes of the polymer may be disposed of to sewer. The Predicted Environmental Concentration based on an Australia-wide use pattern is estimated below:

Amount of polymer discharged to sewer/year:	31,000 kg
National population:	19,000,000
Daily water usage/person	150 L
PEC:	30 µg/L

Exposure levels of this magnitude are of little ecotoxicological concern for poly(aliphatic acid) polymers, such as the notified polymer, which typically have LC₅₀ values >100 mg/L (Boethling and Nabholz, 1997).

If deposited on soil or into landfill, the notified chemical will be mobile with the potential to leach, while if released into waterways it would become associated with the aqueous phase. However, release is expected to be diffuse, thus limiting the potential for adverse environmental effects. Incineration of waste oil containing the notified chemical would destroy the substance with evolution of water vapour and oxides of carbon, nitrogen and sulphur, and sodium compounds that would be assimilated with the ash. Sludges from oil recycling facilities could also be incinerated.

The high water solubility and high molecular weight of the notified polymer indicate little potential for bioaccumulation.

Overall, the environmental risk presented by the introduction of the notified chemical is predicted to be low.

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1. Hazard assessment

An Ames test using the notified polymer showed that it was not mutagenic in bacterial strains. Irritation studies on a product, OS135262 containing 10% the notified polymer indicated the product was a slight skin and eye irritant in rabbits. The notified polymer cannot be classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b) for the endpoints tested.

13.2. Occupational health and safety

Transport and Storage

Under normal working conditions, waterside, transport and storage workers are unlikely to be exposed to the notified polymer and the occupational health risk posed to these workers is considered low.

End use

The notified polymer is imported at 10% in Lubrizol 0805.2. At metalworking plants, Lubrizol 0805.2 will be directly added to the metalworking fluid reservoir at a final concentration of 500 ppm and sprayed onto the cutting edge during the machining operation. Occupational exposure to the 10% notified polymer product may occur during filling, spraying and cleaning up containers. Inhalation exposure is expected to be low as the generation of mist is suppressed during metalworking. Skin and eye contact will be the main routes of exposure. Significant dermal absorption of the notified polymer through intact skin is not expected because of the high molecular weight and low concentration of the notified polymer in metalworking fluid. The potential for mild skin/eye irritation exists for workers exposed to the product. Workers will need to wear overalls, nitrile or neoprene gloves, and safety glasses or goggles.

Conclusion

Risk of adverse health effects due to the notified polymer is low due its expected low toxicity and low exposure potential. However, due to the presence of other components in the formulated products control measures are required to minimize skin and eye contact.

13.3. Public health

The notified polymer and the product containing the notified polymer are not available for sale to the general public. The product containing the notified polymer will be used in metalworking fluids for industrial use. The notified polymer is not likely to be a risk to public health since the potential for public exposure to the notified polymer is negligible.

14. MSDS AND LABEL ASSESSMENT

14.1. MSDS

The MSDS of the notified polymer and product containing the polymer provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). The MSDS for the product Lubrizol 0805.2 is published here as part of the assessment report. The accuracy of the information on the MSDS remains the responsibility of the applicant.

14.2. Label

The label for the notified polymer and products containing the polymer provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of*

Workplace Substances (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

15. RECOMMENDATIONS

Control Measures

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Spillage of the notified polymer should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Protective eyewear, chemical resistant industrial clothing and footwear and nitrile or neoprene impermeable gloves should be used during occupational use of the products containing the notified polymer; where engineering controls and work practices do not reduce vapour and particulate exposure to safe levels, an air fed respirator should also be used.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

15.1 Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
- the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

- (2) Under Section 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

16. REFERENCES

Boethling RS and Nabholz JV. Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Ecological Assessment of Polymers. Hamilton JD and Sutcliffe R ed. Ecological Assessment of Polymers. New York, Van Nostrand Reinhold, pp 187-234

Connell D. W. (1990) General characteristics of organic compounds which exhibit bioaccumulation. In Connell D. W., (Ed) Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA.

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National Occupational Health and Safety Commission (1999b) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Australian Government Publishing Service, Canberra.

Safepharma (2001) OS 142485: Determination of water solubility (SPL Project Number: 525/215), Safepharma Laboratories Ltd, UK.

Safepharma (1999) OS 142485: Reverse mutation assay Ames test" using *Salmonella typhimurium* and *Escherichia coli*, (SPL Project Number: 525/161), Safepharma Laboratories Ltd, UK.

WIL (1997a) Primary dermal irritation study of OS135262A in albino rabbits, WIL-168126, WIL Research Laboratories Inc, USA.

WIL (1997b) Primary eye irritation study of OS135262A in albino rabbits, WIL-168127, WIL Research Laboratories Inc, USA.

Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

<i>Erythema Formation</i>	<i>Rating</i>	<i>Oedema Formation</i>	<i>Rating</i>
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 (Draize *et al.*, 1944) for evaluation of eye reactions is as follows:

CORNEA

<i>Opacity</i>	<i>Rating</i>	<i>Area of Cornea involved</i>	<i>Rating</i>
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

<i>Redness</i>	<i>Rating</i>	<i>Chemosis</i>	<i>Rating</i>	<i>Discharge</i>	<i>Rating</i>
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

<i>Values</i>	<i>Rating</i>
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

Draize, J. H., Woodward, G., Calvery, H. O. (1944) Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, *J. Pharmacol. Exp. Ther.* 82 : 377-390.

Draize J. H. (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49 : 2-56.