File No: PLC/153

February 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Viscoplex 0-350, Viscoplex 5304

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Viscoplex 0-350, Viscoplex 5304

1. APPLICANT

Plastral Fidene Pty Ltd of 11 B Lachlan St Waterloo NSW 2017 and Castrol Australia Pty Ltd of 132 McCredie Rd Guildford NSW 2161 have submitted a Polymer of Low Concern notification statement in support of their application for an assessment certificate for Viscoplex 0-350, Viscoplex 5304.

2. IDENTITY OF THE CHEMICAL

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

Marketing Name: Viscoplex 0-350, Viscoplex 5304

Characterisation as a Synthetic Polymer of Low Concern

Number-Average Molecular Weight (NAMW):	> 1000
Maximum Percentage of Low Molecular Weight Species	
Molecular Weight < 500:	0 %
Molecular Weight < 1 000:	0 %
Polymer Stability	the notified polymer is expected to be stable
Reactivity	no highly reactive functional groups are present
Charge Density	no charged groups are present

The polymer meets the criteria for assessment as a synthetic polymer of low concern under Regulation 4A of the *Industrial Chemicals (Notification and Assessment) Act* (1989).

Method of Detection and Determination: infrared spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer is produced as a solution in mineral oil, containing between 40 % and 70 % notified polymer. The properties given below refer to the solution or the notified polymer, as stated.

Appearance at 20°C and 101.3 kPa:	rubberlike liquid (notified polymer) yellowish liquid with an ester odour (solution)
Boiling Point:	> 200°C (solution)
Specific Gravity:	0.92 at 20°C (solution)
Water Solubility:	< 0.02 % soluble species (notified polymer, see comments below)
Partition Co-efficient (n-octanol/water):	not determined (see comments below)
Hydrolysis as a Function of pH:	not determined (see comments below)
Dissociation Constant:	no dissociable groups are present
Flash Point:	136°C (solution)
Flammability Limits:	not highly flammable; combustible (notified polymer)
Explosive Properties:	not expected to be explosive (notified polymer)
Reactivity/Stability:	expected to be stable under normal environmental conditions (notified polymer)

Comments on Physico-Chemical Properties

The notifier determined the boiling point of the polymer solution to be > 200ºC. The notifier did not determine the vapour pressure of the notified polymer, which would be expected to be very low. However, the vapour pressure of the polymer solution would be expected to be that of the solvent mixture.

The notifier determined the water solubility of the notified polymer to be < 0.02% by weight according to an in-house procedure analogous to the flask shaking method OECD TG 105. The notified polymer has a high molecular weight and lacks polar functionality, so the water solubility is expected to be < 1 mg/L.

The polymer contains ester linkages that could be expected to undergo hydrolysis under extreme pH conditions. However, due to the expected low water solubility, this is unlikely in the environmental pH range of between 4 and 9.

The notifier did not determine the partition coefficient and adsorption/desorption of the

notified polymer. These measurements could not be undertaken as the notified polymer is expected to be insoluble in water and largely partition into n-octanol rather than water. Due to its low water solubility, the polymer is expected to become associated with the organic component of soils and sediments.

The notifier did not determine the dissociation constant of the notified polymer. No groups which are likely to dissociate under normal environmental conditions (4 < pH < 9) are present.

4. PURITY OF THE CHEMICAL

Degree of Purity: 40 – 70 % in mineral oil

Hazardous Impurities: none

Non-hazardous Impurities (> 1% by weight): none

Maximum Content of Residual Monomers: residual monomer identities and concentrations have been exempted from publication; concentrations of residual monomers are all below the relevant cutoffs for the notified polymer to be classified as hazardous

Additives/Adjuvants:

Chemical name:	mineral oil
Synonyms:	hydrocarbon oils
CAS No.:	8020-83-5
Weight percentage:	30 – 60 %

5. USE, VOLUME AND FORMULATION

The two names Viscoplex 0-350 and Viscoplex 5304 refer to the same formulation. The name Viscoplex 0-350 is the one currently in use. The notified polymer will be used in the production of gearbox oils for heavy vehicles. It will initially be imported as a component of formulated oils at a concentration of 1.2 %, although the mineral oil solution containing 40 – 70 % notified polymer may be imported at a later date for production of the oil within Australia. In this case, reformulation will occur at one site, by blending the solution of the notified polymer with oil and other additives to produce the finished oil.

Formulated oils will be imported in 200 L drums, and approximately 30 % of the imported volume will be decanted into 20 L drums at up to 4 sites, for further distribution. The mineral oil solution of notified polymer (Viscoplex 0-350 or Viscoplex 5304) will be imported for reformulation in 5000 to 20000 L bulk containers or 200 L drums.

The notifiers estimate that the import volume will be less than 10 tonnes per annum for the

first five years.

6. OCCUPATIONAL EXPOSURE

Transport and Storage

Transport and storage workers are not expected to be exposed to the polymer solution or to the finished oils during shipment in bulk containers or drums except in the case of an accident involving spillage. These workers may handle the imported oil containing the notified polymer at 1.2 %, or the polymer solution for reformulation, containing the notified polymer at 40 – 70 %.

Reformulation

While the notified polymer will initially be imported as a component of a finished oil, it may at a later date be imported as a solution at 40 – 70 % for local reformulation. The polymer solution will be reformulated by blending with oils and other additives to produce the finished lubricants. The blending will be mostly an automated process in an enclosed system. Additive packages shipped in drums will be transferred into the blend tank by drum pump. During the connection and disconnection of drums, dermal contact with the polymer solution (up to 70 % notified polymer) is possible. During transfer from bulk containers, dermal exposure to drips and spills of the polymer solution is possible during connection and disconnection of transfer hoses. The notifier states that 1 to 2 workers will be involved in the transfer of the notified polymer solution. Sampling of the formulated product will also occur.

The containers used for transferring the notified polymer solution will be cleaned by rinsing with clean lubricating oil. The finished lubricants will be transferred into drums or bulk containers using an automated pumping system. Dermal exposure to drips and spills of the finished oil, containing 1.2 % notified polymer, will be possible during connection and disconnection of transfer hoses. One to two workers are stated to be involved in this process.

The notified polymer has a very low vapour pressure and, as the solution and finished oils are mineral oil based products, they will have high viscosity, minimising the possibility of vapour and aerosol formation. Inhalation is therefore not expected to be an important exposure route. The notifier states that the workers will wear PVC gloves and goggles.

Maintenance workers handling the equipment used for blending and filling may also come into dermal contact with residues containing the notified polymer, should maintenance be required prior to flushing the equipment.

Repackaging

Approximately one third of the finished oil containing the notified polymer will be repackaged into 20 L containers prior to end use. The repackaging will be a semi-automated process, and worker involvement will be restricted to connecting and disconnecting transfer hoses and drum pumps. Dermal exposure to drips and spills of the finished oil, containing 1.2 % notified polymer, is possible during these operations. The notifier states that up to 4 workers will be involved in this process.

End Use

The products containing the notified polymer will be sold in 200 L or 20 L drums to

customers for maintenance of heavy diesel engine powered vehicles. Occupational exposure to the finished containing the notified polymer will occur at a large number of facilities throughout Australia. At each facility, 1 to 2 motor mechanics will be exposed to the finished oil, and dermal and ocular exposure to the notified polymer at a concentration of 1.2 % is possible. The notifier indicates that the transfer of the oil will normally be a semi-automated process. Exposure to the used oil under a wide variety of conditions may be possible during maintenance of mechanical parts which have been in contact with the oil.

7. PUBLIC EXPOSURE

Little public exposure to the notified polymer is expected during transport, storage and commercial use of the notified polymer solution or the finished lubricants containing the notified polymer. Around 5 % (5000 L) of the product containing the notified chemical is expected to reach the retail market, and may be used by members of the public to replenish or top up transmission oil. Consequently, there is likely to be intermittent dermal exposure, with the potential for accidental ocular, oral and inhalation exposure.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier indicates that any waste product generated during the semi-automated decanting process will be handled by licensed waste oil disposal companies and will be disposed of either through oil recycling or incineration. The amount of waste product generated during the semi-automated decanting process is expected to be low.

The lubricant containing the notified polymer sold and transported in the 55 gallon and 20 L drums to customers will be transferred into transmissions of heavy duty diesel vehicles by a semi-automated filling process. The notifier expects that the amount of waste generated during the filling process will be low, and handled in the same manner as described for the decanting process. The amount of waste product generated during the semi-automated filling process is expected by the notifier to be low.

Some waste residue will remain in the ‘empty’ containers after use. It is estimated by the notifier that < 5 % per year of the container contents, or approximately 90 kg of the notified polymer, will remain as residue in the containers. Drums of the product containing the notified polymer will be disposed of by registered waste drum disposal companies by either recycling or landfill.

Environmental releases during normal use are estimated at 4-8 %, as the product is used in a sealed unit. The recommended change interval for transmissions filled with the product containing the polymer will be according to automobile manufacturers’ recommendations, and anticipated to be approximately every 100000 km. The majority of such changes would be carried out by professional repair organisations with trained staff. These centres have controlled handling techniques for the removal and disposal of waste lubricant containing the polymer via approved reclaimers and waste processors. The likelihood of releases of the lubricant from either scrapped vehicle transmissions, motor vehicle accidents, leakage or disposal by “backyard” repairers is unknown although expected to be minimal. The notifier

estimates that 5 % of the notified chemical will reach the retail market.

Release of the lubricant to the environment would only be significant in cases of spills. The Material Safety Data Sheet (MSDS) and material handling instructions provide directions for the proper containment, collection and disposal of wastes, to be done in accordance with local regulations by either incineration or landfill.

Fate

As the notified polymer will be used in sealed systems, environmental exposure is unlikely during use. If there is leakage, product containing notified polymer released to the terrestrial environment would be widespread and difficult to collect. The polymer is highly hydrophobic and will tend either to adsorb to or be associated with soils. It is unlikely that the notified polymer would become a part of the aquatic compartment due to its low water solubility.

The notifier expects that any used and waste lubricant containing the notified polymer will be recycled or disposed of by incineration. Combustion of the notified polymer will produce water and oxides of carbon.

The majority of notified polymer released to the environment would result from spillage of the product at both the decanting and filling stages and from drum residues. These are expected to be handled by licensed oil waste and registered waste drum disposal companies where the waste polymer will be either recycled or incinerated. If the empty drums are not rinsed and recycled, the residues contained within them will end up in landfill, where they will tend to immobilise in soils. The notified chemical is not expected to cross biological membranes, due to the high molecular weight and size, and as such should not bioaccumulate (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

While toxicity data is not a Schedule requirement for Synthetic Polymers of Low Concern, the following analogue toxicology data were submitted for polymers containing long chain alkyl methacrylates in mineral oil, Viscoplex 3-10 and Viscoplex 6-10, Viscoplex 7-30, and Viscoplex 5250. The studies for Viscoplex 7-30 were submitted in German. In addition, a summary of the toxicity of polymers containing the monomer hydroxyethyl methacrylate (HEMA), which is present in the notified polymer but not represented in the analogue polymers, was provided. The analogue studies appear to provide a good overview of the health effects of the class of polymer to which the notified polymer belongs.

9.1 Acute Toxicity

Summary of the acute toxicity of Viscoplex 3-10, Viscoplex 6-10

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 15 mL/kg	(Lightowler & Gardner, 1976)
skin irritation	rabbit	slight irritant	(Lightowler &

			Gardner, 1977b)
eye irritation	rabbit	slight irritant	(Lightowler & Gardner, 1977a)

Summary of the acute toxicity of Viscoplex 7-30

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 20 mL/kg	(Sterner & Chibanguza, 1979a)
acute dermal toxicity	rabbit	LD_{50} > 15 g/kg	(Sterner & Chibanguza, 1982)
skin irritation	rabbit	slight irritant	(Sterner & Chibanguza, 1979c)
eye irritation	rabbit	slight irritant	(Sterner & Chibanguza, 1979b)

Summary of the acute toxicity of Viscoplex 5250

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2000 mg/kg	(Kaufmann, 1991c)
skin irritation	rabbit	non-irritating	(Kaufmann, 1991a)
eye irritation	rabbit	slight irritant	(Kaufmann, 1991b)

9.1.1 Oral Toxicity

(a) Viscoplex 3-10, Viscoplex 6-10 (Lightowler & Gardner, 1976)

Species/strain:	rat/CD
Number/sex of animals:	10/sex for each test sample
Observation period:	14 days
Method of administration:	gavage; dose 15 mL/kg bodyweight (volumetric dose only provided)
Test method:	similar to OECD TG 401
Mortality:	no deaths occurred during the study
Clinical observations:	transient diarrhoea was observed for control animals, treated with mineral oil; no clinical signs of toxicity were seen for either of the test groups

Morphological findings:	no gross abnormalities were seen at necropsy
LD_{50}:	> 15 mL/kg
Result:	the test substances were of very low acute oral toxicity in rats

(b) Viscoplex 7-30 (Sterner & Chibanguza, 1979a)

Species/strain:	rat/Wistar
Number/sex of animals:	10/sex
Observation period:	14 days
Method of administration:	gavage; dose 20 mL/kg bodyweight (50 % test substance in arachis oil)
Test method:	similar to OECD TG 401
Mortality:	no deaths occurred during the study
Clinical observations:	no clinical signs of toxicity were seen
Morphological findings:	no gross abnormalities were seen at necropsy
LD_{50}:	> 20 mL/kg
Result:	the test substance was of very low acute oral toxicity in rats

(c) Viscoplex 5250 (Kaufmann, 1991c)

Species/strain:	rat/Crl.:(WI)BR - Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage; dose 2000 mg/kg bodyweight
Test method:	OECD TG 401
Mortality:	no deaths occurred during the study
Clinical observations:	no clinical signs of toxicity were seen

Morphological findings: no test material related gross abnormalities were seen at necropsy

LD_{50}: > 2000 mg/kg

Result: the test substance was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity

(a) Viscoplex 7-30 (Sterner & Chibanguza, 1982)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 4/sex

Observation period: 14 days

Method of administration: 15 g/kg bodyweight was applied under semi-occlusive conditions to unabraded (2/sex) and abraded (2/sex) skin for 24 hours

Test method: similar to OECD TG 402

Mortality: no deaths occurred during the study

Clinical observations: dermal irritation was observed in all animals; no other clinical signs of toxicity were observed

Draize scores (Draize, 1959):

Time after treatment (days)	***Animal #***							
	1h	***2h***	***3d***	***4d***	***5h***	***6h***	***7d***	***8d***
Erythema	[i]				a	a	a	a
1	1	1	2	2	1	2	3	1
3	1	1	2	1	1	0	2	0
7	1	1	1	1	1	1	1	1
14	2	2	2	2	1	0	2	1
Oedema								
1	1	1	1	1	1	1	1	1
3	1	1	1	1	1	0	1	0
7	2	2	1	1	0	0	0	0
14	1	1	1	1	0	0	0	0

i see Attachment 1 for Draize scales
a abraded skin

Morphological findings: no gross abnormalities were seen at necropsy

LD_{50}: > 15 g/kg

Result: the test substance was of low dermal toxicity in rabbits

9.1.3 Skin Irritation

(a) Viscoplex 3-10, Viscoplex 6-10 (Lightowler & Gardner, 1977b)

Species/strain: rabbit/New Zealand White

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

Observation period: 3 days

Method of administration: 0.5 mL applied to both intact and abraded skin under occlusive conditions for 24 hours; two test samples and mineral oil control were used on separate groups

Draize scores (Draize, 1959):

Viscoplex 3-10

Time after	***Animal #***											
treatment (days)	***1***		***2***		***3***		***4***		***5***		***6***	
Erythema	u	a	u	a	u	a	u	a	u	a	u	a
1	0[i]	1	1	1	1	1	0	1	1	1	1	1
3	1	1	0	1	0	0	0	0	0	0	1	1
Oedema												
1	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0

Viscoplex 6-10

Time after	***Animal #***

treatment (days)	*1*		*2*		*3*		*4*		*5*		*6*	
Erythema	u	a	u	a	u	a	u	a	u	a	u	a
1	1	1	1	1	1	2	1	1	0	1	1	1
3	1	1	1	1	1	2	0	1	0	0	0	0
Oedema												
1	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0

Mineral Oil

Time after treatment (days)	*Animal #* *1*		*2*		*3*		*4*		*5*		*6*	
Erythema	u	a	u	a	u	a	u	a	u	a	u	a
1	0	0	1	1	0	0	0	1	1	1	1	1
3	0	0	0	0	0	0	0	1	0	0	0	1
Oedema												
1	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0

i see Attachment 1 for Draize scales
u unabraded skin
a abraded skin

Test method: US Federal Register 191.11 17 September 1964

Comment: primary irritation indexes were 0.6 for Viscoplex 3-10, 0.8 for Viscoplex 6-10 and 0.4 for mineral oil

Result: the test substances were slightly irritating to the skin of rabbits

(b) Viscoplex 7-30 (Sterner & Chibanguza, 1979c)

Species/strain: rabbit/New Zealand White

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

Observation period: 3 days

Method of administration: 0.5 mL applied to both intact and abraded skin under occlusive conditions for 24 hours

Draize scores (Draize, 1959):

Time after treatment (days)	*Animal #*											
	1		*2*		*3*		*4*		*5*		*6*	
Erythema	u	a	u	a	u	a	u	a	u	a	u	a
1	1	1	1	1	0	0	0	0	1	1	1	1
3	1	1	1	1	0	1	0	0	0	0	1	1
Oedema												
1	0	1	0	1	0	0	0	1	1	1	0	1
3	1	1	0	0	0	1	0	0	0	0	0	1

i see Attachment 1 for Draize scales
u unabraded skin
a abraded skin

Test method: Draize (1959)

Comment: the primary irritation index was 1.08

Result: the test substance was slightly irritating to the skin of rabbits

(c) Viscoplex 5250 (Kaufmann, 1991a)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3 (sex not stated)

Observation period: 3 days

Method of administration: 0.5 mL applied to intact skin under semi-occlusive conditions for 4 hours

Test method: OECD TG 404

Comment: all Draize scores (Draize, 1959) were zero

Result: the test substance was non-irritating to the skin of rabbits

9.1.4 Eye Irritation

(a) Viscoplex 3-10, Viscoplex 6-10 (Lightowler & Gardner, 1977a)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3/sex/group

Observation period: 3 days

Method of administration: 0.1 mL test substance was placed into the conjunctival sac of the left eye; the right eye served as control; two test samples and mineral oil control were used on separate groups

Draize scores (Draize, 1959) of unirrigated eyes:

Viscoplex 3-10

	Time after instillation					
Animal	***1 day***		***2 days***		***3 days***	
Cornea	all Draize scores were zero					
Iris	all Draize scores were zero					
Conjunctiva	***r***	***c***	***r***	***c***	***r***	***c***
1h	0	0	0	0	0	0
2h	0	0	0	0	0	0
3h	0	0	0	0	0	0
4d	0	0	1	0	1	0
5d	1	0	1	0	1	0
6d	0	0	1	0	1	0

Viscoplex 6-10

	Time after instillation					
Animal	***1 day***		***2 days***		***3 days***	
Cornea	all Draize scores were zero					
Iris	all Draize scores were zero					
Conjunctiva	***r***	***c***	***r***	***c***	***r***	***c***
1h	1	0	0	0	0	0
2h	1	0	0	0	0	0
3h	1	0	1	0	0	0
4d	1	0	0	0	0	0
5d	0	0	1	0	0	0
6d	0	0	0	0	0	0

Mineral oil

	Time after instillation		
Animal	***1 day***	***2 days***	***3 days***

Cornea	all Draize scores were zero					
Iris	all Draize scores were zero					
Conjunctiva	***r***	***c***	***r***	***c***	***r***	***c***
1h	0	0	0	0	0	0
2h	1	0	0	0	0	0
3h	0	0	0	0	0	0
4d	0	0	0	0	0	0
5d	0	0	0	0	0	0
6d	0	0	0	0	0	0

see Attachment 1 for Draize scales
r = redness c = chemosis

Test method: US Federal Register 191.12 17 September 1964

Result: the test substances were slightly irritating to the eyes of rabbits

(b) Viscoplex 7-30 (Sterner & Chibanguza, 1979b)

Species/strain: rabbit/New Zealand White

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

Observation period: 7 days

Method of administration: 0.1 mL test substance was placed into the conjunctival sac of the left eye; the right eye served as control

Draize scores (Draize, 1959) of unirrigated eyes:

Time after instillation

Animal	***1 day***		***2 days***		***3 days***	
Cornea	all Draize scores were zero					
Iris	all Draize scores were zero					
Conjunctiva	***r***	***c***	***r***	***c***	***r***	***c***
1	1	1	0	0	0	0
2	1	1	0	0	0	0
3	0	1	0	0	0	0
4	1	2	0	0	0	0
5	1	2	0	0	0	0
6	1	2	0	0	0	0

[1] see Attachment 1 for Draize scales

r = redness c = chemosis

Comment: all Draize scores were zero for the remainder of the observation period; the Draize scores for conjunctival discharge were zero from 24 hours onwards

Test method: Draize (1959)

Result: the notified chemical was slightly irritating to the eyes of rabbits

(c) Viscoplex 5250 (Kaufmann, 1991b)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3 (sex not stated)

Observation period: 3 days

Method of administration: 0.1 mL test substance was placed into the conjunctival sac of the left eye; the right eye served as control

Draize scores (Draize, 1959) of unirrigated eyes:

	Time after instillation							
Animal	***1 hour***		***1 day***		***2 days***		***3 days***	
Cornea	all Draize scores were zero							
Iris	all Draize scores were zero							
Conjunctiva	***r***	***c***	***r***	***c***	***r***	***c***	***r***	***c***
1	1	0	1	0	0	0	0	0
2	1	0	1	0	0	0	0	0
3	1	0	1	0	0	0	0	0

see Attachment 1 for Draize scales
r = redness c = chemosis

Test method: OECD TG 405

Result: the test substance was slightly irritating to the eyes of rabbits

9.2 Summary of Biomedical Applications for Polymers Containing HEMA

A reference (Monthéard et al., 1997) was provided concerning the use of polymers containing hydroxyethyl methacrylate (HEMA) in biomedical applications. The summary referenced a number of studies concerning health effects of these polymers.

Polymers containing high levels of HEMA have been extensively studied for toxicity and biocompatability for purposes of establishing the usefulness of these materials (hydrogels) for applications such as contact lenses, intra-ocular lenses, vascular and other implants and implanted drug delivery systems. A high level of biocompatability was found, although unmodified poly(HEMA) was found to cause inflammatory reactions. No cellular reaction due to residual monomer release was observed when poly(HEMA) was implanted in rat muscle tissue.

The results of these studies indicate that the contribution of HEMA to the acute toxicity of acrylic polymers containing this monomer is low.

9.3 Overall Assessment of Toxicological Data

The submitted analogue toxicity data indicate that the acute oral and dermal toxicity of the notified chemical is likely to be low. The notified polymer has a high molecular weight, and low water solubility, and therefore absorption across biological membranes is not expected. The eye and skin irritation data for the analogues indicate that the notified polymer should be at worst a slight irritant. The analogue polymers were tested in solution in mineral oil, which is similar to the form in which the notified polymer will be imported.

The presence of HEMA, which is not represented in the analogue polymers, in the notified polymer, is not likely to lead to major increases in toxicity and irritancy, on the basis of the information supplied concerning polymers of this monomer.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were submitted.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Waste lubricant generated during the semi-automated decanting and filling processes will be handled by licensed waste oil disposal companies and will be disposed of either through oil recycling or incineration. The amount of waste product generated during the decanting and filling processes is expected to be low.

In the event of accidental spillage of the polymer solution into waterways, the hydrophobic polymer with a high molecular weight is not expected to disperse into the water, but settle out onto sediments. If the polymer is spilt on land, either during usage or transport, it is expected to become immobilised in the soil layer. Contaminated soil can then be collected and disposed to landfill. The use of smaller 20 L container sizes would also limit any hazard in the event of a spill.

Given the above, environmental exposure and the overall environmental hazard is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Viscoplex 0-350, Viscoplex 5304, containing between 40 and 70 % of the notified polymer, is likely to be of very low acute oral and low dermal toxicity, based on analogue studies. The analogues were found to be, at worst, slightly irritating to the eyes and skin of rabbits. No other toxicity studies were submitted, and the notified polymer cannot be assessed against the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). However, due to the high molecular weight and low water solubility of the notified polymer, it is not expected to present a major toxicological hazard.

Occupational Health and Safety
The notified polymer will be imported as a component (at 1.2 %) of a pre-prepared lubricant for use in the gearboxes of heavy vehicles. The lubricant will be imported in 200 L drums, and approximately one third will be repackaged into 20 L drums prior to delivery to customers. The notified polymer may also in future be imported in drums or bulk vessels in solution, containing 40 – 70 % notified polymer. The polymer will then be reformulated in Australia, by blending with oils and other additives. The final product is then repackaged into 20 L or 200 L drums, for delivery to customers.

Dermal exposure would be the predominant route of occupational exposure to the notified polymer. The risk of adverse skin effects following acute exposure to the imported polymer solution (40 – 70 % notified polymer) and finished oil (1.2 % notified polymer) is expected to be low. However, given that there may be some irritant or defatting potential from the polymer and oils, adverse skin effects may ensue if contact is repeated or prolonged. Inhalation exposure is expected to be minimal because the product containing the notified polymer and the finished oil are viscous and therefore have reduced potential to generate aerosols. In addition, the notified polymer has a very low vapour pressure, so vapour accumulation in the workplace air is not likely. Oils containing the notified polymer may be skin irritants, and so protective gloves and clothing should be worn when the possibility exists of exposure to drips and spills. The MSDS indicates that neoprene or nitrile are suitable glove types for mineral oil based products.

The system for reformulating the polymer solution to produce finished lubricants is generally enclosed and automated and the possibility of exposure is therefore limited and typically of short duration. Workers involved in blending the polymer into oil may be exposed to drips and spills of the polymer solution, containing 40 – 70 % notified polymer. Occupational exposure to the drips and spills of the final lubricating oil containing 1.2 % notified polymer is possible for workers handling the finished oil. Workers involved in cleaning and maintenance of tanks and blending equipment may also have general dermal exposure to oil residues. Dermal exposure should be controlled by the use of oil impervious clothing and gloves to minimise the risk of adverse skin effects.

Occupational exposure to the products containing the notified polymer will occur for mechanics filling and topping up the lubricants, and handling mechanical parts which have been in contact with the oil. Dermal and ocular exposure to the notified polymer at a concentration of 1.2 % is possible. Exposure is likely to be of short duration and intermittent, and the filling of the gearboxes is generally semi-automated. It is recommended that the workers wear oil impervious protective clothing and gloves to minimise the risk of adverse skin effects from the finished oil product.

Public Health
Individuals who maintain heavy vehicles and undertake top-ups and fluid changes in their transmissions may have contact with the finished oil containing the notified polymer at 1.2 %. Infrequent dermal, and accidental ocular, oral and inhalation exposure, could occur in these individuals. Given the low toxicity of the notified polymer and the low concentration of polymer in the finished oil, the notified polymer is unlikely to pose a significant hazard to public health. The potential for public exposure during transport, storage, commercial use and disposal of the polymer is expected to be low.

It is therefore considered that the notified polymer will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to Viscoplex 0-350, Viscoplex 5304 the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.2 (Standards Australia, 1990); impermeable gloves or mittens should conform to AS 2161 (Standards Australia/Standards New Zealand, 1998) and be chosen according to the recommendations of the MSDS; all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion;

- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under subsection 64(1) of the Act, secondary notification will be required if the polymer characteristics cease to satisfy the criteria under which it has been accepted as a Synthetic Polymer of Low Concern. Secondary notification of the notified polymer shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

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Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	3 severe	Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe