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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

TLA-1605

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**TLA-1605****1. APPLICANT**

HTX Corporation Pty. Ltd., 17th Floor, 360 Elizabeth Street,
Melbourne, VIC 3000.

2. IDENTITY OF THE CHEMICAL

Trade name: TLA-1605

Number average Molecular Weight: > 1000

The nature of the toxicological profile of the chemical indicate that it is likely to be non-hazardous. Therefore its chemical name, other names, molecular formula, structural formula, lowest number-average molecular weight, monomers, method of detection and determination and spectral data have been exempted from publication in the Assessment Report, Full Public Report and Summary Report.

3. PHYSICAL AND CHEMICAL PROPERTIES

The following data were obtained from tests with TLA-1605 in a form which contains approximately 50% of the notified polymer in diluent oil.

Appearance at 20°C and 101.3 kPa: Red liquid

Odour: Not known

Melting Point/Boiling Point: Not determined

Glass-transition Temperature: Not determined

Specific Gravity: 0.91

Vapour Pressure: < 0.013 kPa at 25°C

Water Solubility:	Not determined
Partition Co-efficient (n-octanol/water):	log P _{o/w} : Not determined
Hydrolysis as a function of pH:	Not determined
Adsorption/Desorption:	Not determined
Dissociation Constant:	Not determined
Flash Point:	182°C (open cup)
Flammability Limits:	Not determined
Combustion Products:	Carbon monoxide, carbon dioxide, aldehydes and ketones
Autoignition Temperature:	Not determined
Explosive Properties:	The polymer is not explosive
Reactivity/Stability:	The polymer will react with strong oxidisers, but is stable under normal use conditions
Kinematic Viscosity:	175 cSt @ 100 °C

Comments on physico-chemical properties:

The notifier states that there are no intermediate streams which contain the final polymer in a concentrated form and is not able to provide analytical and toxicity data on the notified polymer.

The following comments on physico-chemical properties are provided by the notifier:

- . The exact boiling point has not been determined. However, the product has a very high boiling point based on the molecular weight of the synthetic polymer and the diluent oil

- . The vapour pressure is low based on the molecular weight of the polymer and the diluent oil.
- . Water solubility not determined but considered low based on the molecular weight, structure of the polymer and diluent oil. The maximum water solubility of the product estimated to be less than 0.1% in water.
- . Hydrolysis not determined. The polymer should not readily hydrolyse under environmental conditions.
- . Dissociation constant has not been determined. The polymer should have a very low dissociation constant based on the chemical functionality. Also, dissociation would be hard to measure in view of the low water solubility.

4. PURITY OF THE CHEMICAL

Degree of purity of the notified polymer: 88%

Maximum content of residual monomer(s): 1%

Toxic or hazardous impurity:

Chemical name:	Maleic anhydride
CAS No.:	108-31-6
Weight percentage:	below 0.1%
Toxic properties:	LD ₅₀ (oral, rat) = 400 mg/kg (1) Severe eye irritant Sensitiser(1)

The polymer contains up to 10% of a substance which is not classified as a hazardous substance. Its identity has been exempted from publication in these reports.

Additive(s)/Adjuvant(s):

Chemical name:	Petroleum distillates
CAS No.:	64742-65-0
Weight percentage:	about 40-75% of the product

5. INDUSTRIAL USE

The notified polymer is to be used as a lubricant additive. It is a dispersant, which solubilises sludge and inhibits the formation of sludge precursors. The notified polymer will be imported into Australia as an additive package containing 25-60% of the notified polymer.

The product will be imported for sale to lubricant oil formulators for the manufacture and blending of automotive lubricants.

The estimated quantity of the notified polymer to be imported to Australia is 50-500 tonnes in the first year and 50-1500 tonnes per annum over the next four years.

The final lubricant product will contain approximately 3-7% of the notified polymer.

The lubricant additive formulations are presently being marketed in US, Japan, major European countries, South Africa and Central and South America.

6. OCCUPATIONAL EXPOSURE

Most of the product will be imported in bulk, with less than 15% being imported in 205 litre metal drums. The bulk liquid will be shipped in bulk liquid containers in approximately 20 tonne parcels or in chemical parcel tankers in 150 to 400 tonne lots.

The metal drums or bulk tank containers will be shipped to approximately 25 separate locations in Australia for storage and reformulation into the final motor oil product. The number of workers involved in the storage/reformulation of the polymer, at each site, is likely to be in the order of 2-5 people. Handling of the product containing the notified polymer will be for no more than 4 hours a day. Reformulation will involve decanting of the product, blending with lubricating oils and packaging. Blending usually takes place in a stainless steel vessel fitted with a paddle stirrer. The blended lubricating oil containing the notified polymer will then be sold to automotive outlets or the general public.

The major route of exposure to the notified polymer will be dermal. Significant risk of exposure during transport and storage is considered unlikely except in the event of an accidental spillage or leakage as the polymer will be contained in secure containers.

Workers may come into direct contact with the notified polymer during the reformulation process, and dermal contact may be high if personal protective equipment is not used. Mechanics may also come into direct contact with the polymer through handling of lubricating oils containing 3 - 7% of the notified polymer.

7. PUBLIC EXPOSURE

Potential public exposure to the notified polymer or the diluent oil will occur during its handling and use. Home servicing of vehicles would result in dermal exposure to the notified polymer. This practice is conducted infrequently by the public. The major route of exposure to the product, TLA-1605 will be dermal. However, due to the high molecular weight, the notified polymer is not likely to cross biological membranes and induce systemic toxicity.

The notifier states that the product TLA-1605 will be contained within bunded areas for adequate treatment or disposal to prevent entry into sewers and waterways during formulation. The disposal of used oil is a potential source of environmental contamination and thus public exposure.

8. ENVIRONMENTAL EXPOSURE

The crankcase lubricants containing the notified polymer will be used in petrol engines (predominantly passenger car motor vehicles and light commercial vehicles) and diesel engines (approximately 55% total diesel oil sales to on-highway trucks and 45% to off-highway equipment). The off-highway diesel oil sales will comprise approximately 80% for mobile trucking equipment and 20% to stationary equipment largely for power generation in large mining operations.

Distribution of the additive packages containing the notified polymer will be by road and rail.

. **Release**

The imported drums and parcels of the notified polymer in the additive packages will be stored at warehouses and storage locations operated by transport companies and chemical storage companies largely situated in, and around capital cities.

Waste streams containing the notified polymer will be confined to slops, washings and spills and will be contained within bunded areas for adequate treatment or disposal to prevent entry into sewers and waterways.

The notifier states that the spilled material will be washed into a separator, a fully enclosed system comprising a series of baffle units and a skimmer to separate oil or immiscible material from the carrier water stream, followed by a unit consisting of adsorbent polypropylene (oleophilic) mats to remove the oil sheen. The water stream will be further treated to ensure pH, Biological Oxygen Demand (BOD), sulphides etc, comply with the parameters contained in the State Environmental Protection Agency (EPA) license, before discharge to the outfall.

The residues from the skimmer unit will pass to tanks for settling and dewatering, the oil based layer will be incinerated typically as bunker fuel oil. Sludge residues will be mixed with activated clay and taken by licensed industrial waste groups for ultimate disposal by land fill or incineration. Oil or product spills containing the notified polymer may also be treated with solid adsorbent and disposed off in the same manner by licensed industrial waste groups.

In the lube oil blending process it is estimated that typically a 0.2% product loss may be experienced or 40 kg blended oil in a 20 tonne blend batch containing 3-7 weight % of the notified polymer. For example, 3 kg of polymer may be released as slops or washings during transfers to the storage tanks and filling lines, during the unloading of additive from drums or bulk road tankers and during sampling for testing purposes. These liquid releases will be contained and controlled in appropriate compounds or pits for treatment and disposal. Over one year the amount of polymer released would be about 3 tonnes (assuming importation of 1500 tonnes of the notified polymer per annum).

The polymer may also be released to the environment through exhaust emissions, leakage and disposal of used oil.

The notifier states that during engine use the notified polymer will be oxidised to its combustion products. The amount lost, which will not be burned, is probably not measurable, and to the notifier's knowledge has never been determined. The notifier expects this quantity to be no different than with other engine lubricants.

It should be noted that oil emissions with the exhaust are very low (2), and the level of unoxidised polymer is likely to be higher from oil leakage from crankcase lubricated engines and the disposal of used oil.

Oil leaks have a tendency to accumulate in the environment, resulting in a significant environmental load (2). One third of the lubricating oil sold is lost during use; some is lost on the pavement surface, in the streets, roads and car parks. The oil remains on these surfaces until stormwater or the municipal services wash the oil off when it is transported by stormwater drains to waterways or the ocean of urban zones, or to adjacent soils from roads in non-urban areas (3).

The notifier states that losses of the notified polymer during motor oil changes are not expected to be any different from losses experienced with other motor oils. Used lubricant handling guidelines stress minimising personal contact and disposal in an environmentally acceptable manner. However, it should be noted that a report on used lubricating oil in Australia (4) indicates that lubricating oil not collected for recycling or reuse on site as a fuel or lubricant amounts to 22% of total sales. The methods of disposal of used oil include dust and vegetation control, and dumping in sewers and landfill.

. **Fate**

The notifier states that waste polymer from the blending process is prevented from entry into sewers and waterways.

The notified polymer will enter the environment when the waste polymer from the blending process is disposed of by land-fill or incineration. When the polymer is landfilled it is likely to remain at the site of deposition. Leaching of the polymer is unlikely due to its large molecular weight, expected low water solubility and likely adsorption to soil. Incineration of the polymer is unlikely to produce toxic compounds.

The amount of polymer released to the environment through the exhaust emissions is likely to be low as the chemical will be oxidised during combustion and any emissions can be expected to become associated with the soil compartment (including sediment).

Any unoxidised polymer which enters the environment from engine oil leakage and is lost on the pavement surface, in the streets, roads and in car parks, will be washed off (rain or the municipal services) and transported by stormwater drains in the case of urban zones, to water bodies and will become associated with the sediment. When the polymer is washed off roads to adjacent soils, it is likely to accumulate at the site of deposition unless erosion events transport it to water bodies where it is likely to become associated with the sediment.

The fate of the polymer in lubricating oils during use in motor vehicles and diesel trucks compared to off-highway diesel engines is likely to be different. The main difference will occur where off-highway diesel engines are stationary, as this will result in the continual emission of the polymer and products of its combustion at a specific point in the environment.

The amount of unoxidised polymer in used oil is unclear. However, the potential exists for a significant portion of oil containing the polymer to be disposed of in an environmentally unacceptable manner (eg. dust and vegetation control, and dumping in sewers and landfill). Any unoxidised polymer in used oil that is used for dust and vegetation control is likely to remain at the site of application until erosion events transport the polymer to water bodies, where the polymer is likely to become associated with the sediment. The polymer is unlikely to leach when it is dumped at landfills. The dumping of the polymer in sewers is likely to result in the polymer becoming associated with the sludge during treatment.

. **Hydrolysis**

The notifier has stated that the polymer should not readily hydrolyse at ambient temperature based on the structure of the polymer functionality. The polymer does contain a number of groups which may be susceptible to hydrolysis. However, it is unlikely that the polymer will be readily degraded by hydrolysis under environmental conditions because of limited solubility.

. **Biodegradation**

No information has been provided by the notifier. The presence of some linkages in the polymer indicate it would be vulnerable to cleavage in-vivo with subsequent elimination. However, the polymer is unlikely to be readily biodegradable under environmental conditions.

. **Bioaccumulation**

The high molecular weight of the polymer indicates that it is unlikely to bioaccumulate.

9. EVALUATION OF TOXICOLOGICAL DATA

The *Industrial Chemicals (Notification and Assessment) Act 1989* does not require the provision of toxicology data for polymers where the number-average molecular weight exceeds 1,000. Nevertheless, some tests have been conducted on the notified polymer, and were submitted as part of the notification statement. The tests were conducted using the product TLA-1605 which contains approximately 50% of the notified polymer in diluent oil.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of TLA-1605

Test	Species	Outcome	Reference
Skin irritation	Rabbit	Slight irritant	(5)
Eye irritation	Rabbit	Slight irritant	(6)

9.1.1 Skin Irritation (5)

A dose of 0.5 ml of TLA 1605 was applied to three separate sites on each of six New Zealand White rabbits. All sites were clipped free of hair and were located as follows: upper dorsal trunk (intact); lower dorsal (intact) and lower dorsal (abraded). The test compound was occluded under gauze patches on the single upper dorsal site for four hours and on the two lower sites for

24 hours. Observations were made on the upper dorsal site at 30-60 minutes, 24, 48 and 72 hours and daily through day 9 after removal of the gauze patches and on the lower dorsal sites 24, 48 and 72 hours, and daily through day 9, after application. Irritation was scored according to the method of Draize (7).

Slight to well defined redness (erythema) and slight to well defined swelling (oedema), which persisted for up to five days, was observed at all sites in all treated animals. The 24-hour exposure response was observed to be minimal relative to the 4-hour exposure response. The effect of the chemical on abraded skin was slightly less than on intact skin (which is rare). The study did not indicate any interference due to red colour of the product with the assessment of erythema observed in the treated animals.

The results of this study indicate that TLA-1605 is a slight skin irritant at the concentration tested.

9.1.2 Eye Irritation (6)

Six New Zealand White rabbits (three of each sex) received a single 0.1 ml dose of the TLA 1605 in the conjunctival sac of one eye. The other untreated eye served as the control. Treated eyes were examined at 1, 24, 48 and 72 hours after treatment.

Conjunctival effects were apparent after one hour. Moderate redness (erythema), slight swelling (chemosis) and severe discharge were observed in all treated eyes at 1 hour. Effects had decreased by 24 and 48 hours with slight redness and some discharge remaining. All eyes were normal at 72 hours indicating complete reversibility. The test was therefore terminated at 72 hours.

Under the conditions of this study, the notified polymer is considered as slightly irritating to the rabbit eye at the concentration tested.

9.2 Overall Assessment of Toxicological Data

The toxicity data presented indicate that the product is a slight skin and eye irritant. However, these effects are probably due to the diluent oil, known to be a skin and eye irritant, which is present in the product rather than the polymer itself.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Since the chemical being notified is a polymer of greater than 1000 molecular weight, under the *Industrial Chemicals (Notification and Assessment) Act 1989*, environmental effects information is not required.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Although up to approximately 3 tonnes of polymer per annum may be lost from the blending process, the hazard to the environment is likely to be low, due to the release being spread over a number of sites across Australia, and the notifier states that waste will be prevented from entering sewers and waterways. The disposal of the waste polymer from the blending process by landfill or incineration is unlikely to present a hazard to the environment.

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 hazard to the environment from the leaking of oil from engines and the disposal of used oil containing the polymer in an environmentally unacceptable manner (eg. dust and vegetation control, and dumping in sewers and landfills) is likely to be low because:

- . the release will be dispersed across Australia (predominantly in the urban regions) and the environmental concentration of the polymer should be very low (below 1 ppb);
- . the bulk of this release is likely to become associated with soil/sediment;
- . the toxicity of such modified polyisobutylene polymers is low because of low bioavailability; and
- . where the polymer is contained in urban and rural runoff and enters aquatic environments, the expected very low concentration of the polymer and its high molecular weight

(>1000) indicates it is unlikely to present a hazard to organisms inhabiting these environments.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is a high molecular weight polymer (>1000) and therefore unlikely to be absorbed across biological membranes such as the skin, gut and respiratory tract to bring about systemic effects. Toxicity data on the reaction product, TLA-1605 indicate that it is a slight skin and eye irritant. Workers involved in formulating operations (approximately 50% of the notified polymer) and mechanics using motor oils (handling 3-7% of the notified polymer) if sufficiently exposed to the product containing the polymer may suffer skin and eye irritation. The concentrations of the residual monomers present in the polymer are not expected to pose a health hazard.

The physico-chemical properties indicate that the notified polymer is unlikely to present any significant safety hazard to workers.

Significant public exposure to the notified polymer is anticipated as it is to be marketed in a motor oil. Home servicing of vehicles would result in dermal exposure to the notified polymer. As this practice is conducted infrequently by the public, the level of the polymer in the product is considerably low and skin absorption is unlikely; the hazard to the public would be tolerable from this aspect of the chemicals use.

13. RECOMMENDATIONS

When using products containing the notified polymer the following guidelines and precautions should be observed:

- . good work practices should be implemented to avoid splashings or spillages;
- . good housekeeping and maintenance should be practised, spillages should be dealt with promptly with absorbents and discarded according to local or State regulations;

- . spent oil should be discarded according to local or State regulations;
- . good personal hygiene should be observed;
- . when direct contact with the chemical is anticipated, personal protective equipment which complies with Australian Standards should be worn such as splash proof goggles {AS 1336-1982 (8), AS 1337-1984 (9)} gloves {AS 2161-1978 (10)}, and overalls {AS 3765.1-1990 (11)}; and
- . a copy of the Material Safety Data Sheet (MSDS) for TLA-1605 and for products containing it, should be readily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for the reaction product, TLA-1605, was provided (attachment 1) in Worksafe Australia format (12). This MSDS was provided by HTX Corporation Pty. Ltd. as a part of their notification statement. It is reproduce here as a matter of public record. The accuracy of this information remains the responsibility of HTX Corporation Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of the notified polymer in TLA-1605 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**

1. RTECS. Register of the Toxic Effects of Chemical Substances. United States National Institute of Occupational Safety and Health, Cincinnati. Silver Platter CD-Rom, 1992.
2. Van Donkelaar P, "Environmental Effects of Crankcase and Mixed Lubrication", The Science of the Total Environment, 92 (1990), p165-179.
3. Vazquez-Duhalt R, "Environmental Impact of Used Motor Oil", The Science of the Total Environment, 79 (1989), p1-23.
4. Australian and New Zealand Environmental Council, (1991), "Used Lubricating Oil Generation, Recovery and Reuse in Australia", p11.
5. Primary Dermal Irritation Study in Rabbits with L-087-1724.00 (TLA-1605): Study No. PH 420-TX-001-88. Pharmakon Research International, Inc., Waverly, Pennsylvania, 1988.
6. Primary Eye Irritation Study in Rabbits with l-087-1724.00 (TLA-1605): Study No. PH421-TK-006-88. Pharmakon Research International, Inc., Waverly, Pennsylvania, 1988.
7. Draize, J.H., et al., J. Pharm, Exp. Ther. 82 : 377 - 390, 1944.
8. Australian Standard 1336-1982, "Eye protection in the Industrial Environment", Standard Association of Australia Publ. Sydney, 1982.
9. Australian Standard 1337-1984, "Eye protectors for Industrial Applications", Standard Association of Australia Publ. Sydney, 1984.
10. Australian Standard 2161-1978, "Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)", Standard Association of Australia Publ., Sydney, 1978.
11. Australian Standard 3765.1-1990, "Clothing for Protection against Hazardous Chemicals", Standard Association of Australia Publ., Sydney 1990.

12. National Occupational Health and Safety Commission, Guidance Note for Completion of a Material Safety Data Sheet 2nd Edition, AGPS, Canberra, 1990.

NOTES

LABEL: The label does not comply with the Worksafe Australia Labelling Guidance Note, but the low nature of the hazard of this material does not make this a significant concern. compliance with the Guidance Note (especially with regard to risk and safety statements) should be made at the label's next revision.

MSDS: The MSDS is rated as *suitable* for workplace use.

The numbering in, and distinctions of, the main sections in this MSDS are inconsistent with the requirements of the Worksafe Australia Guidance Note. These should be rectified.

The MSDS also contains a number of inconsistencies with:

Viscosity: The package notes 128 cSt, the MSDS notes 175 cSt (both at 100 °C). Presumably, one value is for the notified chemical, the other for the formulated product.

Ingredients: It should be noted that according to the Worksafe Guidance Note for Classifying and Determining a Hazardous Substances, this material is classified as a hazardous substance, by virtue of containing an ingredient with an exposure standard (oil mist).

Health Effects - Eyes: The entry for **Health effects - Eyes** is incorrect. Based on primary irritation data presented in this notification package, the product is a moderate irritant.

First Aid Facilities: The notifying company should give strong consideration to including an entry in this section regarding the availability of eye wash stations wherever this product is used. The present entry in this section is out of context, and should be relocated to **First Aid - Skin**.

These inconsistencies should be rectified.