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September 2010

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Polymer in X-10175

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	Level 7, 260 Elizabeth Street SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

**Director
NICNAS**

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FULL PUBLIC REPORT

This assessment report is for an extension of the original assessment certificate for Polymer in X-10175. Based on the submission of new information by the extension notifier, some sections of the original assessment report have been modified. These modifications have been made under the heading 'Extension Application' in the respective sections.

Polymer in X-10175**1. APPLICANT AND NOTIFICATION DETAILS****APPLICANT(S)**

Afton Chemical Asia Pacific LLC (ABN 99 109 644 288)
Level 9, 20 Berry Street, North Sydney, NSW 2060

Mobil Oil Australia Pty. Ltd. (ABN 88 004 052 984)
29 Francis Street, Yarraville, VIC 3013

Applicant for an Extension of the Original Assessment Certificate:

Perkal Pty Ltd (ABN 43 009 283 363)
14 Beete St
WELSHPOOL WA 6106

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name, Other Names, Molecular Formula, Structural Formula, Molecular Weight, Spectral Data, Composition (including Purity, Identity and Concentration of Hazardous and Non-hazardous Impurities and Additives/Adjuvants, % in Finished Product, Import Volume, Identity of Packaging Site

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Hydrolysis as Function of pH, Dissociation Constant

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (2000)

2. IDENTITY OF CHEMICAL**MARKETING NAME(S)**

X-10175

Extension Application

Mobil Delvac Synthetic ATF (product containing the notified polymer at <2%)

Number Average Molecular Weight (M_n) > 10000 Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

The low level of un-reacted monomers and impurities present as part of the polymer matrix is not expected to be easily extracted.

DEGRADATION PRODUCTS

The notified polymer is not expected to be readily biodegradable in aerobic environments. However, despite the low apparent rate of biodegradation, it is expected that if placed into a landfill (for example after being adsorbed onto sawdust or other adsorbent subsequent to small accidental spills, or when dumped irresponsibly), the substance would be slowly degraded through the slow biological and abiotic processes operative in these facilities. These processes may be expected to produce carbon dioxide, methane, water and oxides of nitrogen.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Pale yellow extremely viscous liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Liquid
Boiling Point	401°C at 102.2 kPa	Measured
Density	977 kg/m ³ at 20°C	Measured
Vapour Pressure	2.0 × 10 ⁻⁸ kPa at 25°C	Measured
Water Solubility	< 5.34 × 10 ⁻⁴ g/L at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	Low water solubility
Partition Coefficient (n-octanol/water)	log Pow > 6.50 (corrected log Pow > 4.05 at pH 7)	Measured
Adsorption/Desorption	log K _{oc} > 5.63	Measured at neutral pH with the test substance ionised.
Dissociation Constant	pKa = 16.2, -0.90 and 9.45	Calculated
Particle Size	Not determined	Liquid
Flash Point	193°C at 100.33 kPa	Measured
Flammability in air	Not determined	Not expected to be flammable in air as it is a high MW liquid.
Autoignition Temperature	364°C	Measured
Explosive Properties	Predicted as negative	Estimated on basis of structure

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity

Notified polymer is stable under normal conditions. Based on the chemical structure, the notified polymer is not expected to have oxidising properties.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

The notified polymer will not be manufactured in Australia. It will be import into Australia in the finished automatic transmission fluid (ATF) containing < 2% of the notified polymer.

Extension Application

The product will be imported into Australia as a finished automatic transmission fluid (ATF) containing < 2% of the notified polymer.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	0-1	1-3	1-3	1-3	1-3
<i>Extension Application</i>					
<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	1	1	1	1	1

PORT OF ENTRY

Port of Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

Mobil Oil Australia Pty. Ltd. and Third Party Packing Service

TRANSPORTATION AND PACKAGING

The finished ATF will be imported (by sea freight) in 208 L drums and then transported by road directly from dockside to the above recipients. After repackaging, finished ATF containing < 2% notified polymer will be transported by road in 20 L pails or 1-5 L plastic containers to the vehicle manufacturing and repair sites.

Extension Application

The finished automatic transmission fluid (ATF) containing <2% of the notified polymer will be imported in intermediate bulk containers (IBCs), 208L drums and 20L packs. The imported finished product containing the notified polymer may be repackaged to 1-4 L plastic containers.

USE

The notified polymer is used as a viscosity modifier in automatic transmission fluids for vehicles (lubricant additive) at < 2%.

OPERATION DESCRIPTION

Repackaging of final Lubricants from shipped drums

The imported finished lubricant containing notified polymer will be repacked from 208 L drums to 20 L pails or 1-5 L plastic containers via a semi-automated dispensing process or to Intermediate Bulk Containers. The bung on the drum is opened and a pump line inserted into the drum and then it is auto-pumped to smaller containers and capped automatically at the completion of the run for smaller packs and manually capped for the IBC's. Packaging workers will place these smaller packages, manually into cardboard cartons and place on pallet. Pallets of smaller packs will be transferred to the general warehouse area for storage until they are transported for use. Prior to initial run of repacking, a sample is taken from the nozzle header and sent to laboratory for QC check. At completion all lines will be flushed with next product to slops tank. Slops will be sent for recycling. Minimal residue will be left in steel drum after pumping. Drums will be bunged and sent to drum recycler.

Extension Application

The imported finished product containing the notified polymer may be repackaged to 1- 4 L plastic containers via semi-automated dispensing processor.

The bungs on the imported drums will be opened and a pump line inserted into the drum and the finished lubricant is then auto-pumped to smaller containers and capped automatically at the completion of the run for smaller packs and manually capped for the IBC's. Packaging workers will place these smaller packages, manually into cardboard cartons and then on to pellets for warehouse storage along with intermediate bulk containers

End use

The lubricant will be applied for automatic transmission applications dependent upon manufacturers' instructions and via internal procedures for Original Equipment Manufacture (OEM) and after-market vehicles. The volume used in OEM and top-ups and the frequency of oil changes will vary significantly between operations & equipment. Used oil will be collected via reservoirs and are expected to be disposed of in accordance with state/government regulations.

The imported polymer is intended for OEM and mechanical workshop use only and that use outside this will be rare or under conditions similar to those of industrial users.

Extension Application

The lubricant containing the notified polymer will be used by industry as well as by general consumers.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Waterside, transport and warehouse workers	small	2-3 hours/day	10 days/year
Re-packaging workers	1	6 hrs/repackage run	Every 4 months
Laboratory workers	1	0.5 hr/sample	Every 4 months
OEM and mechanical workshop	large	variable	variable

EXPOSURE DETAILS

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached. Should a spill occur, it is expected to be contained and collected using suitable absorbents and placed into suitable containers for recovery or disposal in accordance with the MSDS and regulations.

One worker will be exposed to notified polymer (< 2%) during repackaging of polymer in finished lubricant from drums. The potential exposure to the notified polymer would be via skin and eye contact due to the residues and spillage/splashes during connecting/disconnecting pump lines and QC sampling. Exposure during equipment maintenance and cleaning are anticipated to be less frequent and in smaller quantities. It is expected that workers will wear suitable protective clothing, impervious gloves, safety glasses with side shields/chemical goggles and observe safe work practice. All work will be done in well ventilated area. Additionally, copies of the MSDS will be readily accessible in all work areas.

One worker will be exposed to analysis of finished blended lubricant in Laboratory Quality Control check. Dermal and ocular exposure to the notified polymer at concentrations < 2% is possible if there are splashes or spills during the analysis. It is expected laboratory workers will wear laboratory coats, safety glasses and nitrile gloves when analysing the sample.

A large number of industrial workers will be the end users of the gear lubricant. The lubricants will be used in OEM and it will be also used regularly by workers in large and small facilities to top up reservoirs or, less frequently, as a complete lubricant change in gear boxes. Exposure of hands and eyes is likely to the notified polymer, but would be minimised by personnel protective equipment, industrial hygiene and good work practices.

6.1.2. Public exposure

It is unlikely that the public at large will be exposed to the notified polymer, since it will not be sold to the general public. The public may be exposed to the finished automatic transmission fluid (ATF), containing the notified polymer at < 2%, through operations such as adding or changing their vehicle's transmission fluid. However, this too is unlikely since the majority of these operations would be conducted by professional mechanics rather than the general public.

Public exposure to the notified polymer in products as a result of transportation within Australia is unlikely unless there is an accident. The Material Safety Data Sheets supplied for the products containing the notified polymer have instructions for clean-up and disposal of any accidental spills and therefore public exposure as a result of a transport accident is likely to be negligible.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	oral LD50 > 5000 mg/kg bw low toxicity (74% solution in oil)
Rabbit, eye irritation	slightly irritating (74% solution in oil)

Toxicokinetics, metabolism and distribution.

The notified polymer is not expected to be absorbed through the skin, gastrointestinal wall and lungs due to its high molecular weight (>1000 Da) and very small percentage of low molecular weight species < 1000 Da.

Acute toxicity

The notified polymer as 74% solution was of low acute oral toxicity in a study on rats. According to the OECD test guideline the LD50 of the material tested was > 5000 mg/kg bw.

There was no information available on the dermal toxicity of the notified polymer. Given the expected low dermal absorption due to the high molecular weight, dermal toxicity is not expected to be significant.

Irritation

The notified polymer contains a functional group of concern for irritation. In a study provided on rabbits, the notified polymer as 74% solution was considered to be slightly irritating to eyes with a conjunctiva redness score of 1.1.

Classification

Based on the available data on a 75% solution of the notified polymer for acute oral toxicity and eye irritation, the polymer itself is not expected to meet the criteria for classification for these endpoints as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Based on the available toxicological data, the notified polymer as 74% solution was of low oral toxicity and was slightly irritating to eyes. Dermal absorption is expected to be low.

Oral and inhalation exposure is not expected to be significant for workers handling the imported ATF containing < 2% of the notified polymer.

Dermal and ocular exposure to workers during repackaging and end-use would be reduced by engineering controls, the use of personal protective equipment (PPE), and the low concentrations of the notified polymer in the imported product (< 2%). Therefore, the risk to workers is considered low.

Extension Application

As for the original applicant, workers may be exposed to the product containing the notified polymer at <2% during repackaging and end-use applications.

6.3.2. Public health

The risk to the public from incidental contact with ATF containing the notified polymer (< 2%) in automobiles is considered acceptable as the frequency of use will be limited.

Extension Application

As for the original applicant, the product containing the notified polymer at <2% will be used by public as well.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported in 208 litre drums at a concentration of < 2% in automatic transmission fluids (ATF) and will not be manufactured in Australia. Local operations will include transport, storage and repackaging. It is expected that none of the notified polymer in finished lubricant products will be released during transport except from unanticipated release.

During repackaging, the product is repacked from 208 litre drums to 20 litre pails or 1-5 litre plastic containers via a semi-automated dispensing process or to Intermediate Bulk Containers. Significant release of product containing the notified polymer is not expected since process is semi-automated and will be done at a very low frequency. Any spills will be contained within appropriate catchments (i.e. catch pans, bunds) and the spilt material will be soaked up with absorbent material then incinerated at approved facilities or transferred to slop tanks for recycling.

Residual amounts of lubricant will be left in import drums containing < 1% (30 kg per annum) of product but it is expected that the empty drums will be properly bunged and sent to a drum reconditioner.

RELEASE OF CHEMICAL FROM USE

During use of the notified polymer in finished lubricants, the product will be contained within the enclosed gear cases and release is expected to be low. ATFs are changed infrequently and generally only by professional workers, so the incidence of improper disposal should be limited. It is expected that there will be residue left in containers & pails/drums. The drums will be sent to drum reconditioners and any pails and small packs will be disposed of most likely to landfill. It is expected an empty IBC will be collected by manufacturer from the place of use for recycling.

Any release or spills occurring on work sites should be recovered properly and disposal must be in accordance with applicable laws and regulations.

It is expected that all disposal will occur in accordance with MSDS & State regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer released or spilled at the repackaging site or during application will be recovered and disposed of properly and most likely to landfill.

Empty drums should be completely drained, properly bunged and returned to a drum reconditioner. All containers should be disposed of in an environmentally safe manner and most likely to landfill.

It is assumed that skilled tradesmen in industry will be undertaking all maintenance of equipment so therefore any used oil generated from engine repair or changeover will be disposed appropriately.

7.1.2 Environmental fate

The imported polymer is intended to be used in automobile manufacture factory fill operations, or top-ups and full oil changes in after market vehicles.

The residual notified polymer in empty drums may be cleaned and collected at reconditioners and finally be thermally decomposed into oxides of carbon, nitrogen and water. Residue remains in small empty packaging will be disposed of to landfill. Release or spills occurring on work site or during application will be recovered properly and disposal must be in accordance with applicable laws and regulations.

The notified polymer predominantly contained in used oil will share the fate of the used ATF and be collected via reservoirs

It is expected be recycled, refined, burnt as low grade burner fuel or disposed of by incineration. The residual notified polymer contained in equipment at the end of its life is expected to enter metal recycling and finally be thermally decomposed into oxides of carbon, nitrogen and water.

The notified polymer is not expected to be readily biodegradable in aerobic environments. Notified polymer that is disposed of to landfill would be slowly degraded through the slow biological and abiotic processes, and may finally be expected to produce carbon dioxide, methane, water and oxides of nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

The calculation of a PEC has not been undertaken as the low water solubility and proposed use pattern in ATFs of the notified polymer will lead to low aquatic exposure.

7.2. Environmental effects assessment

No ecotoxicity data were submitted. The notified polymer contains potentially cationic functionalities which are known to be toxic. However, the limited aquatic release and FGEW of around 5000 would limit the hazard to the aquatic compartment.

7.3. Environmental risk assessment

The notified polymer is not considered to pose an unacceptable risk to the aquatic environment based on its reported use pattern and FGEW of around 5000.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

and

Similarly, it is not possible to categorise the notified chemical according to the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) for either health or environmental effects.

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is considered not to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is considered not to pose an unacceptable risk to public health.

Environmental risk assessment

On the basis of the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Risk assessment and recommendations relating to Extension Application

The use and the fate of the notified polymer will not change under the proposed extension. The increase in proposed introduction volume is not expected to significantly change the environment and health impacts. Therefore, there are no changes required in the existing risk assessment and recommendations.

Recommendations

REGULATORY CONTROLS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
 - Avoid eye contact
 - Avoid skin contact
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
 - Protective eyewear
 - Impervious gloves
 - Protective clothing

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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of to landfill or by re-refining or authorised incineration.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a viscosity modifier in automatic transmission fluids for vehicles (lubricant additive) at < 2%, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 3 tonnes per year, or is likely to increase, significantly;
 - if the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet

The MSDS of the products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

Extension Application

The extension applicant has provided an MSDS for a product containing the notified polymer. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Boiling Point** 401 ± 0.5 °C at 102.2 kPa

Method OECD TG 103 Boiling Point.
ASTM E537-86

Remarks It was determined using differential scanning calorimetry.

Test Facility SafePharm Laboratories Ltd (2007a)

Density 977 kg/m^3 at 20 ± 0.5 °C

Method OECD TG 109 Density of Liquids and Solids.

Remarks It was determined using pycnometer.

Test Facility SafePharm Laboratories Ltd (2007a)

Vapour Pressure 2.0×10^{-8} kPa at 25°C

Method OECD TG 104 Vapour Pressure.

Remarks It was determined using a vapour pressure balance between 240-250°C. It is reasonable considering the molecular weight of the polymer being $> 10,000$.

Test Facility SafePharm Laboratories Ltd (2007b)

Water Solubility $< 5.34 \times 10^{-4}$ g/L at 20 ± 0.5 °C

Method OECD TG 105 Water Solubility.

Remarks It was determined by Flask Method with analysis by GPC. A calculated value was $< 3.09 \times 10^{-17}$ g/L, which is more indicative of the expected very low solubility.

Test Facility SafePharm Laboratories Ltd (2007a)

Hydrolysis as a Function of pH Not determined

Remarks The measurement could not be conducted due to the low water solubility. The hydrolysis behaviour of the notified polymer should not be a concern in the environmental pH range of 4-9 despite the presence of hydrolysable functionality.

Test Facility SafePharm Laboratories Ltd (2007a)

Partition Coefficient (n-octanol/water) $\log \text{Pow} > 6.5$, corrected as > 4.05 at pH 7

Method OECD TG 117 Partition Coefficient (n-octanol/water).

Remarks HPLC Method used. The dead time was determined by using Thiourea. The column temperature was set as 30°C. The partition coefficient has been tested as $\log \text{Pow} > 6.5$, as it eluted after DDT, and corrected as > 4.05 at pH 7 (run at pH 12). High Pow is expected according to the low water solubility of the notified polymer.

Test Facility SafePharm Laboratories Ltd (2007a)

Adsorption/Desorption $\log K_{oc} > 5.63$
– screening test

Method OECD TG 121 Estimation of the Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC).

Remarks HPLC screening method was used. Column temperature was set as 30°C. Testing was carried out at neutral pH with the test substance ionised, as testing pH of 11 to 14 when the substance presents in its unionised form is outside the environmental range. High K_{oc} is expected from the high Pow and the low water solubility of the notified polymer.

Test Facility SafePharm Laboratories Ltd (2007a)

Dissociation Constant $\text{pK}_a = 16.2 \pm 0.46, -0.90 \pm 0.70$ and 9.45 ± 0.28

Remarks As no experimental testing was deemed possible because of incompatibility of test substance with the 3 methods referenced in OECD TG 112, it was therefore considered appropriate to estimate the dissociation constant of the test substance through computer-based estimation software, Advanced Chemistry Development, ADC/1-Lab Web service (ACD/pKa 8.03). The notified polymer is likely to be ionised through out the environmental pH range of 4-9.

Test Facility SafePharm Laboratories Ltd (2007a)

Flash Point $193 \pm 2^{\circ}\text{C}$ at 100.33 kPa

Method EC Directive 92/69/EEC A.9 Flash Point.

Remarks It was determined using a closed cup equilibrium method.

Test Facility SafePharm Laboratories Ltd (2007b)

Autoignition Temperature $364 \pm 5^{\circ}\text{C}$

Method EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).

Remarks It was determined by heating aliquots of the test substance in a flask and observing for any ignition.

Test Facility SafePharm Laboratories Ltd (2007b)

Explosive Properties

Method EC Directive 92/69/EEC A.14 Explosive Properties.

Remarks Based on the chemical structure and oxygen balance of the test substance, the result for the explosive properties has been predicted as negative.

Test Facility SafePharm Laboratories Ltd (2007b)

Oxidising Properties

Method Method A21 of Commission Directive 2004/73/EC (which constitutes Annex V of Council Directive 67/548/EEC)

Remarks Based on the chemical structure, the result for the oxidising properties has been predicted negative.

Test Facility SafePharm Laboratories Ltd (2007b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Mixture of oil and notified polymer (74%)
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Sprague Dawley
Vehicle	Corn oil
Remarks - Method	No protocol deviations occurred during this study.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5 per sex	5000	0

LD50	> 5000 mg/kg bw
Signs of Toxicity	Clinical abnormalities observed during the study included decreased defecation, soft stools, fecal staining and dark material around the facial area.
Effects in Organs	No gross internal findings were observed at necropsy.
Remarks - Results	

CONCLUSION The notified polymer at 74% is of low toxicity via the oral route.

TEST FACILITY Springborn Laboratories, Inc. (2002)

B.2. Irritation – eye

TEST SUBSTANCE	Mixture of oil and notified polymer (74%)
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	2 M, 4 F
Observation Period	7 days
Remarks - Method	There were no protocol deviations.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Conjunctiva: redness</i>	1.1	2	72 hours	0
<i>Conjunctiva: chemosis</i>	0	1	< 24 hours	0
<i>Conjunctiva: discharge</i>	0	3	< 24 hours	0
<i>Corneal opacity</i>	0	0	-	0
<i>Iridial inflammation</i>	0	0	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results	<p>All animals survived throughout the study.</p> <p>No iridial or corneal changes were seen. All six animals had moderate to severe discharge after 1 hour and the discharge was all resolved after 24 hours. All six animals had slight to moderate conjunctival redness. Five animals had positive scores for conjunctival redness at 1 and/or 24 hours only, and all six animals were free of all ocular irritation within 7 days after instillation of the test substance.</p> <p>The notified polymer is not considered an eye irritant according to OECD</p>
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criteria, but is considered an eye irritant according to OSHA (Occupational Safety and Health Administration) criteria.

CONCLUSION

The notified polymer at 74% is slightly irritating to the eye.

TEST FACILITY

Huntingdon Life Sciences (2000)

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