

File No: LTD/1739

April 2014

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

PUBLIC REPORT

Polymer in OMA 600

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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.

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

This 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**

TABLE OF CONTENTS

SUMMARY	3
CONCLUSIONS AND REGULATORY OBLIGATIONS	3
ASSESSMENT DETAILS.....	5
1. APPLICANT AND NOTIFICATION DETAILS.....	5
2. IDENTITY OF CHEMICAL.....	5
3. COMPOSITION	5
4. PHYSICAL AND CHEMICAL PROPERTIES	6
5. INTRODUCTION AND USE INFORMATION.....	6
6. HUMAN HEALTH IMPLICATIONS	7
6.1. Exposure Assessment.....	7
6.1.1. Occupational Exposure.....	7
6.1.2. Public Exposure.....	8
6.2. Human Health Effects Assessment	8
6.3. Human Health Risk Characterisation	8
6.3.1. Occupational Health and Safety.....	8
6.3.2. Public Health.....	9
7. ENVIRONMENTAL IMPLICATIONS.....	9
7.1. Environmental Exposure & Fate Assessment	9
7.1.1. Environmental Exposure.....	9
7.1.2. Environmental Fate	9
7.1.3. Predicted Environmental Concentration (PEC).....	9
7.2. Environmental Effects Assessment.....	9
7.2.1. Predicted No-Effect Concentration.....	10
7.3. Environmental Risk Assessment.....	10
<u>APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES</u>	<u>11</u>
<u>APPENDIX B: TOXICOLOGICAL INVESTIGATIONS.....</u>	<u>13</u>
B.1. Acute toxicity – oral.....	13
B.2. Irritation – skin	13
B.3. Genotoxicity – bacteria	14
BIBLIOGRAPHY.....	16

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1739	A. S. Harrison & Co Pty Ltd	Polymer in OMA 600	ND*	< 100 tonnes per annum	Fuel additive

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer cannot be classified as hazardous according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment

Provided that adequate PPE is used to minimise exposure to workers handling the notified polymer as imported, under the conditions of the occupational settings described the notified polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment

On the basis of its limited aquatic exposure and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
 - Coveralls
 - Gloves
 - Safety goggles
 - Respiratory protection if conditions occur where mists are likely to be generated

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

- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical/polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS) as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by 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 polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer 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(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1,000 Da;
 - the concentration of the polymer exceeds or is intended to exceed 0.15% in fuel additives.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from fuel additive, or is likely to change significantly;
 - the amount of polymer being introduced has increased, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer 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.

(Material) Safety Data Sheet

The SDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

A.S. Harrison & Co Pty Ltd (ABN 89 000 030 437)
75 Old Pittwater Rd
BROOKVALE NSW 2100

NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn \geq 1,000 Da (similar to a chemical previously assessed by NICNAS).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS number, structural formulae, polymer constituents, residual monomers, impurities and additives/adjuvants

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Partition Co-efficient, Adsorption/Desorption, Dissociation Constant and Flammability Limits

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

OMA 600 (product containing the notified polymer at < 20%)

MOLECULAR WEIGHT (MW)*

Number Average Molecular Weight (Mn)	1,096 Da
Weight Average Molecular Weight (Mw)	1,388 Da
Polydispersity Index (Mw/Mn)	1.266
% of Low MW Species < 1,000 Da	33.5%
% of Low MW Species < 500 Da	3.3%

* Molecular weight for analogue polymer that only differs in counterion.

MOLECULAR FORMULA

Unspecified

ANALYTICAL DATA

Reference GPC and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

74.5%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

None

DEGRADATION PRODUCTS

The notified polymer is stable under normal conditions. Degradation products are expected to be oxides of nitrogen and carbon.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: viscous brown liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< -20 °C	Measured
Boiling Point	Not determined	Decomposed between 180 °C and 202 °C.
Density	945 kg/m ³ at 20 °C 953 kg/m ³ at 15 °C	Measured
Vapour Pressure	0.077 kPa at 20 °C	Measured
Water Solubility	0.0345 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality. However, due to its low water solubility, it is expected to hydrolyse slowly in the environmental pH range (4–9) at ambient temperature.
Partition Coefficient (n-octanol/water)	Not determined	Could not be tested as the notified polymer is a surfactant and is expected to accumulate at the phase interface of octanol and water.
Adsorption/Desorption	Not determined	Expected to adsorb to soil, sediment and sludge based on its low water solubility, high molecular weight and presence of cationic functionality.
Dissociation Constant	Not determined	The notified polymer is a salt and is expected to be ionised under environmental conditions.
Particle Size	Not determined	Liquid
Flash Point	83.5 °C (pressure unknown)	Measured
Flammability	Not flammable	Measured
Autoignition Temperature	401 °C	Measured
Explosive Properties	Not determined	Not expected to be explosive based on structure.
Oxidising Properties	Not determined	Not expected to be oxidising based on structure.
Dynamic viscosity	1.44 × 10 ⁴ mPa.s at 20 °C 1.04 × 10 ³ mPa.s at 40 °C	Measured

DISCUSSION OF PROPERTIES

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

Reactivity

The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as part of fuel additive packages at < 20% concentration.

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

Year	1	2	3	4	5
Tonnes	< 100	< 100	< 100	< 100	< 100

PORT OF ENTRY

Sydney, Melbourne, Brisbane and Perth

IDENTITY OF RECIPIENTS

Fuel refineries

TRANSPORTATION AND PACKAGING

The notified polymer will be imported as part of fuel additive packages in 200 kg drums, 1,000 kg intermediate bulk containers (IBCs) and 20 tonne bulk ISO tanks.

USE

The notified polymer will be used as a fuel additive at up to 0.15% concentration.

OPERATION DESCRIPTION

The additive package (which contains the polymer at < 20% concentration) will be added to the fuel at the refinery and/or fuel distribution terminal, prior to the transport of the fuel to retail stations. The additive package will typically be added to the fuel either by continuous injection into a fuel line or by batch addition of the notified polymer into a fuel storage tank, at up to 0.15% concentration.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage of OMA 600	6–8	125–225
Blender	6–8	125–225
QA analysis	6–8	125–225
Transport and storage of fuel	6–8	125–225
End-use fuelling	10–30 minutes	200

EXPOSURE DETAILS

The potential routes of occupational exposure are dermal and ocular. Inhalation exposure is not expected as the polymer has low vapour pressure and the generation of mists or aerosols is not expected.

Transport and storage

Transport workers are not expected to be exposed to the imported product containing the notified polymer at < 20% concentration, as they will be handling closed containers. Dermal or ocular exposure is possible in the event of an accident where the packaging is breached or during transfer to storage tanks.

Blending

At the fuel manufacturer's refinery terminal, blending of the notified polymer with refined fuel will be carried out automatically or semi-automatically in a closed system, usually through metering into tank trucks. Exposure to the notified polymer may occur from accidental spillage. Exposure is expected to be low and further reduced by workers wearing personal protective equipment when handling fuel.

Worker exposure to the notified polymer at up to 0.15% concentration may also occur during sampling and analysis of blended fuel at the refinery or during maintenance of refinery plant or pipelines. The exposure would be limited by appropriate personal protective equipment worn by workers.

Transport and storage of fuel

Dermal or ocular exposure to drips and spills of fuel containing the notified polymer at up to 0.15% concentration is possible during the connection and disconnection of transfer hoses. Exposure is expected to be limited during transportation as the protocols of loading and unloading are done with minimal spills. The drivers also usually wear gloves and long sleeves shirts when unloading the fuel.

End users of fuel

Personnel from commercial trucking fleet, marine tugs or small ships, agriculture users, railroads, service stations, truck stops and construction companies may be exposed to fuel containing the notified polymer at up to 0.15% concentration during handling and fueling of the vehicles. As most of the notified polymer will be combusted with the fuel, exposure is expected to be minimal during end-use.

6.1.2. Public Exposure

The public will not have exposure to the imported product containing the notified polymer at < 20% concentration, as it will be used in industrial settings.

The public may have incidental skin or eye contact with fuel containing the notified polymer at up to 0.15% concentration through operations such as refilling vehicles.

Other exposures to the imported product or fuel containing the notified polymer could only occur in the unlikely event of an accident where import containers or the tank trucks are ruptured.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on an analogue chemical (a polymer previously assessed by NICNAS) are summarised in the table below. Details of the studies can be found in Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics

Polymers with Mn > 1,000 Da and low water solubility are poorly absorbed across biological membranes. However, the notified polymer contains a high proportion of low molecular species < 1,000 Da and a small amount of low molecular species < 500 Da and therefore, the potential for limited absorption via the dermal, oral and inhalation routes exists.

Acute toxicity

The analogue polymer is of low acute toxicity via the oral route.

Irritation

The analogue polymer was slightly irritating to skin, consistent with the structural alert for irritation (Hulzebos, 2005). The notified chemical contains the same structural alert as the analogue polymer and may be slightly irritating to the skin.

Sensitisation

The notified polymer is cationic, which is a structural alert for sensitisation (Barratt, 1994). Therefore, the notified polymer may be a skin sensitiser.

Mutagenicity

The analogue polymer was not mutagenic with or without metabolic activation in the bacterial reverse mutation study.

Health hazard classification

Based on the available data the notified polymer cannot be classified as hazardous according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation**6.3.1. Occupational Health and Safety**

The toxicological properties of the notified polymer have not been fully investigated. However, the notified polymer is a cationic polymer structurally identical to the analogue polymer and differs only in the counter ion used. Therefore, based on structural alerts present in the analogue and notified polymer, the notified polymer may be a skin sensitiser.

Dermal and ocular exposure will be the main routes of worker exposure to the notified polymer (< 20% as imported and up to 0.15% in fuel). The notifier states that exposure to the notified polymer is expected to be minimised by various control measures, including engineering controls (closed systems) and PPE (coveralls, safety goggles, impervious gloves). Based on the predicted low toxicity and the assessed use, and provided that adequate PPE is used to minimise dermal exposure to workers handling the notified polymer as imported (at < 20% concentration), the risk to workers of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The public are expected to have similar but less frequent potential than workers for exposure to the notified polymer (at < 0.15% concentration). Use of PPE is not expected; however, engineering controls employed at fuel stations are expected to minimise exposure to the notified polymer. Therefore, the risk to the public from the use of the notified polymer is not expected to be unreasonable.

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 as a component of fuel additive packages and is expected to be blended with fuels at industrial facilities in Australia. Reformulation sites such as fuel refineries are expected to have cleaning and disposal procedures compliant to industry standards. Thus, release to the aquatic environment is unlikely during reformulation activities. Environmental release during importation, reformulation, transport and distribution may occur as a result of accidental spills. The container filling processes are computer automated, so minimal spills due to loading are expected. In the event of a spill, the notified polymer should be contained, collected and disposed of in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

The fuels containing the notified polymer are expected to be available at retail fuel outlets. The notified polymer is consumed during the combustion of the fuel to generate primarily water and oxides of carbon and nitrogen.

RELEASE OF CHEMICAL FROM DISPOSAL

International Standards Organisation (ISO) tanks, Intermediate Bulk Containers (IBCs) and drums containing the notified polymer are anticipated to be sent for cleaning and reconditioning by a licensed company. The resultant washings from such companies are expected to be sent to an on-site waste treatment facility and any waste sludge is likely to be sent to landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted. Most of the notified polymer in fuel will be consumed and degraded during use. Minor amounts of the notified polymer are expected to be released to landfill as residues in containers or treatment wastes. Release to the aquatic compartment is unlikely based on the reported use pattern. In landfill, the notified polymer is not expected to be mobile or bioavailable due to its high molecular weight, low water solubility and presence of cationic functional groups. It is not expected to be biodegradable based on its structure. The notified polymer is unlikely to cross biological membranes due to its high molecular weight. Therefore, it is unlikely to be bioaccumulative. The notified polymer is expected to degrade by slow biotic and abiotic processes in landfill, or by thermal decomposition, to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentration (PEC) has not been calculated since no significant release of the notified polymer to the aquatic environment is expected from the reported use pattern.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymer. The notified polymer has functionality that has the potential to be toxic to aquatic life. However, no significant exposure of the notified polymer to aquatic organisms is expected based on the reported use pattern.

7.2.1. Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) has not been calculated for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.3. Environmental Risk Assessment

Calculation of the Risk Quotient (PEC/PNEC) is not possible since neither the PEC nor the PNEC is available. The majority of the notified polymer will be thermally decomposed during its use as an additive in fuels. Exposure to the aquatic compartment is unlikely based on the reported use pattern. On the basis of its limited aquatic exposure and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Melting Point/Freezing Point** < -20 °C

Method OECD TG 102 Melting Point/Melting Range.
 Remarks Differential scanning calorimetry was used.
 Test Facility Innospec Limited (2013)

Boiling Point Not determined

Method OECD TG 103 Boiling Point.
 Remarks Differential scanning calorimetry and thermogravimetric analysis were used. The test substance decomposed between 180 °C and 202 °C.
 Test Facility Innospec Limited (2013)

Density 945 kg/m³ at 20 °C
953 kg/m³ at 15 °C

Method OECD TG 109 Density of Liquids and Solids.
 Remarks Pycnometer cup method was used.
 Test Facility Innospec Limited (2013)

Vapour Pressure 0.077 kPa at 20 °C

Method EC Council Regulation No 440/2008 A.4 Vapour Pressure.
 Remarks Static method was used. Chilworth Technology Limited at Hampshire, UK conducted the test.
 Test Facility Innospec Limited (2013)

Water Solubility 0.0345 g/L at 20 °C

Method OECD TG 105 Water Solubility (modified method).
 Remarks EC Council Regulation No 440/2008 A.6 Water Solubility.
 A small amount of test substance was weighed into a 50 mL centrifuge tube and approximately 45 mL of deionised water added to it. The mixture was stored at ambient temperature (20–25 °C). After 3 days the mixture was centrifuged and then filtered. The resulting clear filtrate was then diluted 50:50 v/v with isopropyl alcohol. UV-Visible spectrophotometry was used as the method of quantitation of soluble test substance in the aqueous media.
 Initial testing indicated that the notified polymer formed a stable emulsion in water which could not be broken down using centrifugation or filtration.
 Test Facility Innospec Limited (2013)

Flash Point 83.5 °C (pressure unknown)

Method EC Council Regulation No 440/2008 A.9 Flash Point.
 Remarks Pensky-Martens closed cup flash point apparatus was used.
 Test Facility Innospec Limited (2013)

Flammability Not flammable

Method EEC directive: 67/548/EEC, Annex V, method 10 Flammability (Solids/Gels/Pastes).
 Remarks The sample ignited briefly under an ignition source (high pressure gas torch) and was immediately extinguished so sustained burn could not be achieved. Further application of the flame to the melted material did not produce any effect.
 Test Facility Innospec Limited (2013)

Autoignition Temperature 401°C (including barometric pressure correction factor)

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks Chilworth Technology Limited at Hampshire, UK conducted the test.
Test Facility Innospec Limited (2013)

Viscosity 1.44×10^4 mPa.s at 20 °C
 1.04×10^3 mPa.s at 40 °C

Method OECD TG 114 Viscosity of Liquids.
Remarks A cone and plate rotational rheometer was used.
Test Facility Innospec Limited (2013)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Analogue polymer (a polymer previously assessed by NICNAS)
METHOD	OECD TG 420 Acute Oral Toxicity – Fixed Dose Procedure. EC Council Regulation No 440/2008 B.1 bis Acute toxicity (oral) fixed dose method.
Species/Strain	Rat/Wistar
Vehicle	Arachis oil BP
Remarks - Method	No protocol deviation.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	1 F	300	0
2	1 F	2000	0
3	4 F	2000	0

LD50	> 2,000 mg/kg bw
Signs of Toxicity	There were no signs of systemic toxicity.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	All animals showed expected gains in bodyweight.

CONCLUSION	The analogue polymer is of low toxicity via the oral route.
------------	---

TEST FACILITY	Harlan Laboratories Ltd (2011a)
---------------	---------------------------------

B.2. Irritation – skin

TEST SUBSTANCE	Analogue polymer (a polymer previously assessed by NICNAS)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Council Regulation No 440/2008 B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 M
Vehicle	None
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No protocol deviation. One rabbit was initially treated. One patch was removed at each of three time points: 3 minutes, 1 hour and 4 hours after application.

RESULTS

<i>Lesion</i>	<i>Mean Score* Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	1.0	1.0	1.3	2	< 7 days	0
<i>Oedema</i>	0.7	0.3	0.7	1	< 72 hours	0

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

Remarks - Results	3-Minute exposure period and 1-Hour exposure period Very slight erythema was noted at the treated skin site at the 24, 48 and 72-hour observations. The treated skin site appeared normal at the 7-day
-------------------	---

observation.

4-Hour exposure period

Very slight erythema was noted at one treated skin site immediately and one hour after patch removal. Well-defined erythema and very slight oedema were noted at two treated sites and very slight erythema and very slight oedema were noted at one treated skin site at the 24-hour observation. Very slight erythema with or without very slight oedema, was noted at all treated skin sites at the 48-hour observation. Very slight erythema was noted at two treated skin sites at the 72-hour observation.

One treated skin site appeared normal at the 72-hour observation and all three treated skin sites appeared normal at the 7-day observation.

CONCLUSION

The analogue polymer is slightly irritating to the skin.

TEST FACILITY

Harlan Laboratories Ltd (2011b)

B.3. Genotoxicity – bacteria

TEST SUBSTANCE

Analogue polymer (a polymer previously assessed by NICNAS)

METHOD

OECD TG 471 Bacterial Reverse Mutation Test.

EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.

Plate incorporation procedure/Pre incubation procedure

Species/Strain

S. typhimurium: TA1535, TA1537, TA98, TA100

E. coli: WP2uvrA

Metabolic Activation System

Rat liver S9-mix induced by combination of phenobarbitone and β -naphthoflavone.

Concentration Range in Main Test

Test 1 (plate incorporation procedure)

With and without metabolic activation: 0, 50, 150, 500, 1500, 5000 μ g/plate

Test 2 (pre-incubation procedure)

With and without metabolic activation: 0, 5, 15, 50, 150, 500, 1500, 5000 μ g/plate

Vehicle

Dimethyl sulphoxide

Remarks - Method

No protocol deviation.

RESULTS

Metabolic Activation	Test Substance Concentration (μ g/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>	> 5,000			
Test 1		5,000	5,000*	negative
Test 2		$\geq 1,500$	≥ 500	negative
<i>Present</i>	> 5,000			
Test 1		5,000	5,000*	negative
Test 2		$\geq 1,500$	≥ 500	negative

*Opaque test substance film was observed at 5,000 μ g/plate.

Remarks - Results

In the first test (plate incorporation procedure) the test substance caused a visible reduction in the growth of the bacteria background lawn and/or substantial reductions in the frequency of revertant colonies for all of the *Salmonella* strains at 5,000 μ g/plate in both the absence and presence of S9-mix. No toxicity was noted to *Escherichia coli* strain WP2uvrA at any test substance dose level. In test 2 (pre-incubation procedure) the test substance induced toxicity as weakened bacterial background lawns to all of the tester strains initially from 1,500 μ g/plate in both the absence and presence of S9-mix. These results were not indicative of toxicity

sufficiently severe enough to prevent the test substance being tested up to the maximum recommended dose level of 5,000 µg/plate. An opaque test substance film was noted at 5,000 µg/plate in test 1 (plate incorporation procedure). However, in the second test (pre-incubation procedure) a white, particulate precipitate was noted at and above 500 µg/plate. Neither of these observations prevented the scoring of revertant colonies.

No significant increases in the frequency of revertant colonies were recorded for any of the strains of bacteria, at any dose level either with or without metabolic activation or exposure method.

All of the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION

The analogue polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

Harlan Laboratories Ltd (2011c)

BIBLIOGRAPHY

- Barratt, M.D., Basketter, D.A., Chamberlain, M., Payne, M.P., Admans, G.D., Langowski, J.J. (1994) Development of an expert system rulebase for identifying contact allergens. *Toxicology In Vitro*. 8:837-839.
- Harlan Laboratories Ltd (2011a) Analogue Polymer: Acute Oral Toxicity in the Rat - Fixed Dose Method (Project Number 41100746, 11 August 2011). Harlan Laboratories Limited, Derbyshire, UK (Unpublished report submitted by the notifier).
- Harlan Laboratories Ltd (2011b) Analogue Polymer: Acute Dermal Irritation in the Rabbit (Project Number 41100747, 11 August 2011). Harlan Laboratories Limited, Derbyshire, UK (Unpublished report submitted by the notifier).
- Harlan Laboratories Ltd (2011c) Analogue Polymer: Reverse Mutation Assay "AMES Test" Using Salmonella Typhimurium and Escherichia Coli (Project Number 41100750, 24 August 2011). Harlan Laboratories Limited, Derbyshire, UK (Unpublished report submitted by the notifier).
- Hulzebos E, Walker JD, Gerner I and Schlegel K (2005) Use of Structural Alerts to Develop Rules for Identifying Chemical Substances with Skin Irritation or Skin Corrosion Potential. *QSAR Comb. Sci.* 24, 332-342.
- Innospec Limited (2013) Physical Characteristics of OMA 600. (Report No. RT0038-P REV0, 6 December 2013). Innospec Limited, Cheshire, UK (Unpublished report submitted by the notifier).
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html>.