

File No: EX/201
(LTD/1601)

August 2015

**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	4
1. APPLICANT AND NOTIFICATION DETAILS	5
2. IDENTITY OF CHEMICAL.....	5
3. COMPOSITION.....	5
4. PHYSICAL AND CHEMICAL PROPERTIES	5
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.....	7
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	8
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	9
7.3. Environmental Risk Assessment	9
<u>APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES</u>	<u>11</u>
<u>APPENDIX B: TOXICOLOGICAL INVESTIGATIONS</u>	<u>12</u>
B.1. Acute toxicity – oral.....	12
B.2. Irritation – skin.....	12
B.3. Genotoxicity – bacteria	13
BIBLIOGRAPHY	15

Public Report

This assessment report is for an extension of original assessment certificate for Polymer in OMA 600. Based on the submission of new information by the extension notifier, the original assessment report has been modified.

SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
EX/201 (LTD/1601)	BP Australia 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 under the Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)], or the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations 2009).

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 the limited aquatic exposure and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers 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 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.

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 amount of polymer being introduced has increased from 100 tonne per year, or is likely to increase, significantly;
- the concentration of the polymer exceeds or is intended to exceed 0.03% in fuel additives;
- the polymer has a number-average molecular weight of less than 1000 Da.

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

Extension Application:

The applicant for the extension application has not provided a MSDS. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Holder of Original Assessment Certificate (LTD/1601)

A.S. Harrison & Co Pty Ltd (ABN: 89 000 030 437)

75 Old Pittwater Rd, Brookvale NSW 2100

Applicant for an Extension of the Original Assessment Certificate:

BP Australia Pty Ltd (ABN: 53 004 085 616)

717 Bourke Street, Melbourne VIC 3008

NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn \geq 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS number, molecular formula, structural formula, polymer constituents, residual monomers/impurities and import volume

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%)

ANALYTICAL DATA

Reference GPC and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 50 %

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	< -20 °C	Measured
Boiling Point	208 °C at 101.32 kPa	Measured
Density	951 kg/m ³ at 20 °C 950 kg/m ³ at 15 °C	Measured
Vapour Pressure	0.1 kPa at 20 °C	Measured
Water Solubility	< 0.017 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 will tend to accumulate at the phase interface of octanol and water. Expected to have a high partition coefficient on the basis of its low water solubility.
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. However, it is unlikely to be dissociated under environmental conditions due to its low water solubility.
Particle Size	Not determined	Liquid
Flash Point	98 °C	Measured
Autoignition Temperature	343.5 °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 and oxygen balance calculation.
Dynamic viscosity	4.4 × 10 ⁸ mPa.s at 20 °C 6.19 × 10 ⁷ mPa.s at 40 °C	Measured

DISCUSSION OF PROPERTIES

Reactivity

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

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

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%.

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

Total volume for original notifier and extension applicant

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	< 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, 1000 kg intermediate bulk containers (IBCs) and 20 tonne bulk ISO tanks.

USE

The notified polymer will be used as a fuel additive at < 0.03%.

OPERATION DESCRIPTION

The additive package (which contains the polymer at < 20%) is added to the fuel at the refinery and/or fuel distribution terminal, prior to the transport of the fuel to the retail stations. The additive package is typically 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 0.03%.

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, ocular and inhalation. However inhalation exposure is not expected as the polymer has low vapour pressure, and the generation of mists/aerosols is not expected.

Transport and storage of OMA 600

Transport workers are not expected to be exposed to the imported OMA 600 containing the notified polymer at < 20%, 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 OMA 600 with refined fuel is carried out automatically or semi-automatically in a closed system, usually through metering into tank trucks. Exposure to OMA 600 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 < 0.03% 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 < 0.03% 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 < 0.03% 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 OMA 600 containing the notified polymer at < 20%, as it is used in limited industrial settings.

The public may have incidental skin or eye contact with fuel containing the notified polymer at < 0.03% through operations such as refilling vehicles.

Other exposures to the imported OMA 600 or fuel could only occur in the extremely unlikely event of an accident where import containers or the tank trucks are ruptured, liberating OMA 600 or fuel containing the notified polymer.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer 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 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics

Polymers with Mn > 1000 Da and low water solubility are poorly absorbed across biological membranes. However, the notified polymer contains a high proportion of low molecular species < 1000 Da and a small amount of low molecular species < 500 Da. and as such, the potential for limited absorption via the dermal, oral and inhalation routes exists.

Acute toxicity

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

Irritation

The notified polymer was slightly irritating to skin, consistent with the structural alert for irritation (Hulzebos, 2005).

Sensitisation

The notified polymer is cationic, which is a structural alert for sensitisation (Barratt, 1994). Therefore the notified polymer may possess some sensitising properties.

Mutagenicity

The notified 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 under 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, based on structural alerts, sensitisation is possible.

Dermal and ocular exposure will be the main routes of worker exposure to the notified polymer (< 20% as imported and < 0.03% in fuel). Exposure is expected to be reduced by various control measures, including engineering controls and PPE already in place for handling fuel. 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 risk to the public from exposure to the notified polymer in fuel is not expected to be unreasonable based on the low concentrations of the notified polymer in the fuel (< 0.03%) and the expected low exposure to the fuel.

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

ISO tanks, IBCs and drums are anticipated to be sent for cleaning and reconditioning by a licensed company. The resultant washings from such companies are typically passed 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 and low water solubility. It is not expected to be biodegradable based on its structure but, as the notified polymer is unlikely to cross biological membranes due to its high molecular weight, 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.

8. RISK ASSESSMENT FOR EXTENSION APPLICATION

The total introduction volume and the proposed use of the notified chemical will not change under the proposed extension. Therefore, the circumstances in the extension application are not expected to impact on the original human health and environmental risk assessment and recommendations.

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 (2011)

Boiling Point 208 °C at 101.3 kPa

Method OECD TG 103 Boiling Point.
Remarks Differential scanning calorimetry was used.
Test Facility Innospec Limited (2011)

Density 951 kg/m³ at 20 °C
950 kg/m³ at 15 °C

Method OECD TG 109 Density of Liquids and Solids.
Remarks Pycnometer cup method was used.
Test Facility Innospec Limited (2011)

Vapour Pressure 0.1 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 (2011)

Water Solubility < 0.017 g/L at 20 °C

Method OECD TG 105 Water Solubility.
Remarks Column Elution Method.
Test Facility Innospec Limited (2011)

Flash Point 98 ± 1 °C

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 (2011)

Autoignition Temperature 343.5 °C (including barometric pressure correction factor)

Method ASTM E659-78
Remarks Chilworth Technology Limited at Hampshire, UK conducted the test.
Test Facility Innospec Limited (2011)

Dynamic viscosity 4.4 × 10⁸ mPa.s at 20 °C
6.19 × 10⁷ 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 (2011)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Acute toxicity – oral**

TEST SUBSTANCE	Notified polymer
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	> 2000 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 notified polymer is of low toxicity via the oral route.
------------	---

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

B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer
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 notified polymer is slightly irritating to the skin.

TEST FACILITY

Harlan Laboratories Ltd (2011b)

B.3. Genotoxicity – bacteria

TEST SUBSTANCE

Notified polymer

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>	> 5000			
Test 1		5000	5000*	negative
Test 2		≥ 1500	≥ 500	negative
<i>Present</i>	> 5000			
Test 1		5000	5000*	negative
Test 2		≥ 1500	≥ 500	negative

*Opaque test substance film was observed at 5000 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 5000 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 1500 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 5000 µg/plate. An opaque test substance film was noted at 5000 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 notified 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) Notified 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) Notified 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) Notified 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 (2011) Physical Characteristics of OMA 600. (Report No. RT0004-P REV0, 13 May 2011). Innospec Limited, Cheshire, UK (Unpublished report submitted by the notifier).
- NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia
- 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>.