

File No: LTD/1561

May 2012

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

PUBLIC REPORT

PC-5

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 Sustainability, Environment, Water, Population and Communities.

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:

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**Director
NICNAS**

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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
LTD/1561	DIC Australia Pty Ltd Hewlett Packard Australia Pty Ltd	PC-5	ND	≤ 2 tonnes per annum	Component of inks and coatings

*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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment

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 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 implement the following engineering controls during reformulation to minimise inhalation exposure to the notified polymer in powder premix (< 20%):
 - Local exhaust ventilation
- Employers should ensure that the following personal protective equipment is used by workers during reformulation to minimise inhalation exposure to the notified polymer in powder premix (< 20%):
 - Respiratory protection
- Service personnel should wear impermeable gloves when removing spent printer cartridges containing the notified polymer and during routine maintenance and repairs.

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

- Spray applications should be carried out in accordance with the Safe Work Australia *National Guidance Material for Spray Painting* [NOHSC (1999)] or relevant State and Territory Codes of Practice.
- 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 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 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 1000;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from being a component of ink for industrial use, imported in closed cartridges, or a component of paint for industrial use, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 2 tonnes per annum, 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 MSDSs of the products containing the notified polymer were provided by the applicants. The accuracy of the information on the MSDSs remains the responsibility of the applicants.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

DIC Australia Pty Ltd (ABN 12 000 079 550)
42 Sunmore Close
Heatherton VIC 3202

Hewlett Packard Australia (ABN 74 004 394 763)
31 – 41 Joseph Street
Blackburn VIC 3130

NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn ≥1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: CAS number, chemical name, molecular formula, structural formula, molecular weight, analytical data, degree of purity, hazardous and non-hazardous impurities/residual monomers, additives/adjuvants, polymer constituents, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada (2008) US (1991), EU (1991), EU REACH (2008) Korea (2011) Japan (2011)

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

PC-5

CH116A HP Designjet 788 Cyan
CH119A HP Designjet 788 Black
CH120A HP Designjet 788 Light Cyan
CH130A HP Scitex FB240 Cyan
CH133A HP Scitex FB240 Black
CH135A HP SC200 Cyan
CH136A HP SC200 Magenta
CH138A HP SC200 Black
CH216A HP Scitex FB250 Cyan
CH219A HP Scitex FB250 Black
CH220A HP Scitex FB250 Light Cyan
Solarflex
Solarsleeve
Solarcat

ANALYTICAL DATA

Reference UV/vis, FT-IR, NMR and GC-MS/GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

The polymer is stable under normal condition of use.

DEGRADATION PRODUCTS

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

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: blue paste

Property	Value	Data Source/Justification
Melting Point	Not determined	Decomposes prior to melting from approximately 316 °C.
Boiling Point	Not determined	Decomposes prior to melting.
Density	$1.38 \times 10^3 \text{ kg/m}^3$ at 22 °C	Measured
Vapour Pressure	$1.9 \times 10^{-8} \text{ kPa}$ at 25 °C	Measured
Water Solubility	$1.93 \times 10^{-4} \text{ g/L}$ at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	Not expected to hydrolyse based on its low solubility in water

Partition Coefficient (n-octanol/water)	$\log K_{ow} \geq 6.50$	Measured
Adsorption/Desorption Dissociation Constant	$\log K_{oc} \geq 5.63$ Not determined	Measured The notified polymer may have functionality expected to be ionised at environmental pH (4-9).
Particle Size	Not determined	The notified polymer is a paste.
Solid flammability	Not highly flammable	Measured
Autoignition Temperature	334 °C	Measured
Explosive properties	Not determined	Predicted negative
Oxidising properties (solids)	Not determined	Predicted negative
Surface Tension	Not determined	Water solubility < 1 mg/L

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 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 a component of ink within printer cartridges at < 5%, or as a component of automotive paint premixes at 2-20% in powder form for reformulation in Australia, or as a component of automotive paint at < 2%.

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

Year	1	2	3	4	5
Tonnes	≤ 1	1 – 2	1 – 2	1 – 2	≤ 2

PORT OF ENTRY

Melbourne, Victoria

IDENTITY OF RECIPIENTS

Recipient sites are located in Victoria.

TRANSPORTATION AND PACKAGING

The transport of ink cartridges containing the notified polymer in ink at < 5% and of automotive paint containers containing the notified polymer at < 2% will be by road.

The imported paint premixes as containing up to 20% notified polymer in 20 kg cardboard boxes on pallets, will be transported by road.

USE

Component of inkjet inks and OEM coatings

OPERATION DESCRIPTION

Ink in printer cartridges

No manufacture or reformulation will occur in Australia. Sealed ink cartridges containing the notified polymer at < 5% will be distributed to commercial and industrial centres for use in printing, and will be handled by service technicians only during replacement of cartridges and service of printers.

Coatings for OEM

At coating formulation sites, the imported powdered premixes containing the notified polymer (at up to 20%) will be blended with the other paint components. Following quality control analysis, the formulated paints (containing < 2% notified polymer) will be transferred to containers for distribution to end-users.

The end-use paint products containing the notified polymer (at < 2%) will be used in original equipment manufacturer (OEM) paint application facilities. The paints will be applied to vehicles by spray.

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>
<i>Ink in printer cartridges</i>		
Importation/Waterside	< 8	10-50
Storage and Transport	< 8	10-50
Office worker	10 seconds/day	2
Service Technicians	1	170
<i>Coatings for OEM</i>		
Transport and storage	1	4
Paint formulation process operator	2.5	40
Quality control	0.5	40
Packaging	2	40
End use	1	60

EXPOSURE DETAILS

Ink in printer cartridges

Storage and transport workers will only handle the sealed cartridges containing the notified polymer and therefore exposure is not expected unless the packaging is accidentally breached.

Service technicians may be exposed to the ink containing the notified polymer (< 5%) when replacing used ink cartridges and repairing and cleaning ink jet printers. Dermal exposure is expected to be the most likely route of exposure. Instructions on how to replace the cartridges safely will be included with the cartridge to minimise exposure. However, occasional dermal exposure during use of the printer may occur if the printed pages are handled inadvertently before the ink dries, or if ink-stained parts of the printer are touched. Once the ink dries, the polymer would be bound in the print matrix, and would not be bioavailable.

Coatings for OEM

Transport and storage workers may come into contact with the imported paint premixes containing the notified polymer (at up to 20%) and formulated paints (containing < 2% notified polymer), only in the unlikely event of an accident.

During paint formulation processes, including transfer, quality control and cleaning and maintenance tasks, dermal, ocular and inhalation exposure to the notified polymer as part of a powdered premix may occur. Exposure is expected to be minimised through the use of local exhaust ventilation and the use of personal protective equipment (PPE), including chemical goggles, impervious gloves and appropriate industrial clothing. With the above controls in place and the expected low volatility of the notified polymer, significant inhalation exposure during reformulation is not anticipated.

At end-use sites, dermal, ocular and/or inhalation exposure to the coatings containing the notified polymer (at < 2% concentration) may occur during transfer, application and cleaning processes. The potential for exposure should be minimised through the use of PPE (goggles, impervious gloves, appropriate clothing) by workers and use of respiratory protection during spray application. Once cured, the notified polymer is not expected to be bioavailable and further dermal contact should not lead to exposure.

6.1.2. Public Exposure

Ink in printer cartridges

The inks containing the notified polymer at < 5% will not be sold to the public. After application to the paper and cured, the notified polymer is expected to remain bound to the paper and will not be bioavailable.

Coatings for OEM

Coatings containing the notified polymer at < 2% are intended for industrial use only and will not be sold to the public. Furthermore, once the coatings have cured and dried, the notified polymer will be reacted into the polymer matrix and will not be bioavailable.

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	LD50 > 2000 mg/kg bw low toxicity
Mutagenicity – bacterial reverse mutation (2 studies)	non mutagenic

Toxicokinetics, metabolism and distribution

Dermal absorption of the notified polymer is expected to be limited by the high molecular weight (> 1,000 Da) and low level of low molecular weight species.

Acute toxicity

As the acute oral LD50 was > 2000 mg/kg bw in rats, the notified polymer was considered to be of low toxicity via the oral route.

Mutagenicity

The notified polymer was not mutagenic with or without metabolic activation in two bacterial reverse mutation studies.

Health hazard classification

Based on the data provided, the notified polymer cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Only limited toxicological data is available on the notified polymer and the risk of health effects cannot be ruled out. The results on the endpoints tested (acute oral toxicity and bacterial mutagenicity) indicate low hazard for these endpoints. The risk of systemic effects from exposure to the notified polymer is expected to be reduced by its high molecular weight ($> 1,000$ Da).

Ink in printer cartridges

Service technicians handling ink products containing the notified polymer ($< 5\%$) may have frequent dermal exposure to the notified polymer, particularly during manual replacement of ink containers, cleaning of ink residues and servicing the printing machine. However, the exposure is expected to be limited by the sealed cartridge packaging, nature of the printing process and the low concentration of the notified polymer within the ink ($< 5\%$). The use of adequate PPE (i.e., impervious gloves) further reduces the risk from exposure. Once the ink is applied to the substrate and dried, the notified polymer would not be bioavailable.

Overall the risk to workers from use in printing is not considered to be unreasonable.

Coatings for OEM

During reformulation workers will handle the notified polymer at concentrations of up to 20%, however exposure is expected to be low, if workplace engineering controls and PPE are used. During application of the coatings, there is potential for inhalation, dermal and ocular exposure to automobile paints containing the notified polymer at concentrations $< 2\%$. Exposure to the notified polymer during end use applications is expected to be low due to the reduced concentration and the use of engineering controls and appropriate PPE.

Overall the risk to workers from use in coatings is not considered to be unreasonable.

6.3.2. Public Health

Ink in printer cartridges

The inks containing the notified polymer at $< 5\%$ will not be sold to the public. The public may have contact with the dried printed materials, however the notified polymer will be bound in the print matrix and will not be bioavailable. Therefore, exposure of the public to the notified polymer is not expected, and the risk is not considered unreasonable.

Coatings for OEM

Paint products containing the notified polymer will not be sold to the public. The public may experience dermal exposure to automobiles to which paint containing the notified polymer has been applied. However, exposure is not expected as the notified polymer ($< 2\%$) will be bound within the paint film. Therefore the risk to the public from the notified polymer is not considered 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 into Australia as a component of ink printer cartridges and automotive paint products. No manufacturing or repackaging of the notified polymer will take place in Australia. Environmental release of the notified polymer is unlikely to occur during importation, storage and transportation as containers are designed to minimise release. In the event of an accidental spill the ink or paint containing the notified polymer is expected to be collected and disposed of via a licensed waste contractor.

RELEASE OF CHEMICAL FROM USE

Ink preparations

Up to 25% of the notified polymer will be imported as a component of ink in cartridges and it is expected that < 1% of the annual import volume of the notified polymer may be spilt. If leakage or spillage does occur, the ink is expected to be physically contained with absorbent material and disposed of to landfill. The ink cartridges will be contained within the printer until the contents are consumed. The empty cartridges, estimated to contain < 1% of the annual import volume of notified polymer, will be removed and disposed of to landfill or sent to the manufacturer for recycling.

Automotive paints

Up to 85% of the notified polymer is expected to be used in automotive paints. When coating formulations containing the notified polymer are applied by spray techniques, it is anticipated that up to 30% of the coating product will form overspray and be collected as waste material. As the application of coatings will be conducted at industrial sites in designated spray booths, the overspray will be captured in the spray booth and on kraft paper or newspaper and is expected to be disposed of to landfill. Equipment used to apply the coating formulations may be rinsed with water or other appropriate solvents. It is estimated that up to 1% of notified polymer used in coatings may be released to sewers in equipment washings. During automotive use of the notified polymer, it is estimated that < 1% of the notified polymer will be spilt. These spills are expected to be contained and disposed to landfill. Less than 1% of the notified polymer may remain as residues in the end-use containers. These are expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Ink preparations

The majority of notified polymer used in ink preparations will be bound to printed paper and, once the ink has dried, will be contained in an inert matrix. It is assumed that 50% of the waste paper will end up in landfill and the rest will undergo paper recycling processes. During recycling processes, waste paper will be repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. Based on its low water solubility, the notified polymer is expected to partition to sludge generated during the recycling process and this is expected to be sent to landfill for disposal.

Automotive paints

The notified polymer remaining in cured paints is trapped in an inert matrix and is expected to share the fate of automotive articles to which it has been applied. The notified polymer is likely to be either thermally decomposed during metal reclamation processes or disposed of to landfill at the end of the useful life of the article.

7.1.2. Environmental Fate

No environmental fate data were provided. The coatings containing the notified polymer will be applied to substrates and cured and hence the notified polymer is not expected to be bioavailable. The majority of the notified polymer is expected to be disposed of to landfill where it will degrade by biotic and abiotic processes to form water and oxides of carbon, nitrogen and sulfur and metal salts.

Approximately half of the paper to which the ink containing the notified polymer is applied to will be recycled. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. However, the notified polymer is cured into the ink matrix and is unlikely to be released into the supernatant waters during recycling processes. The majority of the cured notified polymer is anticipated to sorb to sludge and sediment. Notified polymer in landfilled sludge is expected to degrade biotically and abiotically.

7.1.3. Predicted Environmental Concentration (PEC)

Predicted Environmental Concentrations (PECs) for ocean and river have been calculated assuming that 13.5% (i.e. half of the 25% used in printing inks and 1% from coating equipment washings) of the total import volume of notified polymer would be released to sewers with 85% removal of the notified polymer by sewerage treatment plants (STPs) estimated by SimpleTreat (EC, 2003). In the absence of data, it was assumed in the SimpleTreat model that the notified polymer would not degrade in STPs. It was also assumed the release of the notified polymer will occur over 260 days per annum into the total Australian effluent volume. This corresponds to release from industrial and recycling processes only on working days, based on a 5 day work week.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	2000	kg/year
Proportion expected to be released to sewer	13.5%	
Annual quantity of chemical released to sewer	270	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1.04	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	85%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.034	µg/L
PEC - Ocean:	0.0034	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 1.952 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m³ and a soil-mixing zone of 10 cm, the concentration of the notified polymer may approximate 0.013 mg/kg in applied soil. This assumes that degradation of the notified polymer occurs in the soil within 1 year from application. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated biosolids application, the concentration of notified polymer in the applied soil in 5 and 10 years may approximate 0.065 mg/kg and 0.13 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. Due to its measured low water solubility and demonstrated adsorption to particulates, the notified polymer is not expected to be present at ecotoxicologically significant concentrations in the aquatic compartment. The notified polymer is not anticipated to cross biological membranes due to its high molecular weight and is therefore not expected to bioaccumulate.

7.2.1. Predicted No-Effect Concentration

Since no ecotoxicity data were submitted and very low exposure of the notified polymer to aquatic compartment is expected, the predicted no effect concentration (PNEC) was not calculated.

7.3. Environmental Risk Assessment

The potential for exposure of the notified polymer to the aquatic environment is very low because the majority will be disposed to landfill or thermally decomposed during metal recycling. The risk for harm to aquatic organisms due to washings to the sewer, as a result of paper recycling, is mitigated by the notified polymer's lack of potential to bioaccumulate, insolubility in water and high propensity to adsorb to particulate matter. Taking into account the low exposure to aquatic organisms, the notified polymer is therefore not expected to pose an unreasonable risk to the environment based on its proposed use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Melting Range Not determined

Method ASTM E537-86, compatible with OECD TG 102 Melting Point/Melting Range.
 Remarks Differential scanning calorimetry was used.
 The test substance decomposed prior to melting from approximately 316 °C.
 Test Facility Harlan Laboratories Ltd (2010a)

Density $1.38 \times 10^3 \text{ kg/m}^3$ at $22.0 \pm 0.5 \text{ °C}$

Method OECD TG 109 Density of Liquids and Solids.
 Remarks Gas comparison pycnometer was used.
 Test Facility Harlan Laboratories Ltd (2010a)

Vapour Pressure $1.9 \times 10^{-8} \text{ kPa}$ at 25 °C

Method EC Directive 440/2008 A.4 Vapour Pressure.
 Remarks A vapour pressure balance was used.
 Test Facility Harlan Laboratories Ltd (2010b)

Water Solubility $1.93 \times 10^{-4} \text{ g/L}$ at $20 \pm 0.5 \text{ °C}$

Method OECD TG 105 Water Solubility
 Remarks Column Elution Method. Following two preliminary tests and a full test according to the flask method, the column elution method was used for the definitive test. The flask method resulted in variable results due to the formation of dispersions of test substance with shaking and also the presence of more soluble impurities. Water soluble impurities were removed from the test substance by elution for 10 days. As there was no shaking in the elution test, no dispersions of test substance was formed. The test substance concentration was determined by HPLC.
 Test Facility Harlan Laboratories (2010a)

Partition Coefficient (n-octanol/water) $\log K_{ow} \geq 6.50$

Method OECD TG 117 Partition Coefficient (n-octanol/water)
 Remarks HPLC Method. The partition coefficient was determined by interpolation from a calibration curve constructed from known standards ($\log K_{ow}$ range 0.3 – 6.5) in accordance with the guidelines above. As some components of the test substance had high affinity for the stationary phase of the column the mobile phase was ramped to 100% THF shortly after the retention time of the highest K_{ow} standard (DDT, $\log K_{ow} = 6.5$). It was found that 83.7% of the test substance had $\log K_{ow} \geq 6.50$ by percentage area normalisation. The method guidelines specify that the method is not applicable surface active substances, however the result is consistent with expected properties of the test substance.
 Test Facility Harlan Laboratories (2010a)

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

Method OECD TG 121: Estimation of the Adsorption Coefficient (K_{oc}) on Soil and Sewage Sludge using High Performance Liquid Chromatography
 Remarks HPLC Method. The adsorption coefficient was determined by interpolation from a calibration curve constructed from known standards ($\log K_{oc}$ range 1.25 – 5.63) in accordance with the guidelines above. It was found that 64.4% of the test substance had $\log K_{oc} > 5.63$ and 35.6% had $\log K_{oc} < 1.25$ by percentage area normalisation. The low K_{oc} components were possibly partially reacted components of the test substance that maybe have been ionised/significantly water soluble and therefore rapidly eluted from the column. The method guidelines specify that the method may not work with surface active

substances however the result is consistent with expected properties of the test substance.
Test Facility Harlan Laboratories (2010a)

Solid Flammability Determined to be not highly flammable

Method EC Directive 440/2008 A.10 Flammability (Solids).
Remarks The test substance failed to propagate combustion in the preliminary screening test.
Test Facility Harlan Laboratories Ltd (2010b)

Autoignition Temperature 334°C

Method EC Directive 440/2008 A.16 Relative Self-Ignition Temperature for Solids.
Remarks The test substance was heated in an oven.
Test Facility Harlan Laboratories Ltd (2010b)

Explosive Properties Predicted negative

Method EC Directive 440/2008 A.14 Explosive Properties.
Remarks Based on the value for the decomposition energy and the broadness of the exotherm revealed by differential scanning calorimetry thermogram.
Test Facility Harlan Laboratories Ltd (2010b)

Oxidizing Properties Predicted negative

Method EC Directive 4 A.17 Oxidizing Properties (Solids).
Remarks There are no chemical groups within the structure of the test substance that would imply oxidising properties.
Test Facility Harlan Laboratories Ltd (2010b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar strain Crl:WI (Han)
Vehicle	Water
Remarks - Method	No significant deviation from the protocol.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity	Hunched posture was noted for all animals on day 1. Blue faeces were noted for animals on day 2. The finding was considered to be related to staining properties of the test substance and not toxicologically significant.
Effects in Organs	No abnormalities were found at macroscopic post mortem examination of the animals.
Remarks - Results	The body weight gain shown by the animals over the study period was considered to be similar to that was expected or normal untreated animals of the same age and strain.

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

TEST FACILITY Notox B.V. (2009a)

B.2. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 440/2008 B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA
Metabolic Activation System	Rat liver S9-mix induced by combination of phenobarbital and β -naphthoflavone.
Concentration Range in Main Test	a) With metabolic activation: 0, 10, 33, 100, 333, 1000 μ g/plate b) Without metabolic activation: 0, 10, 33, 100, 333, 1000 μ g/plate
Vehicle	Ethanol
Remarks - Method	No deviation from the protocol. The dose range finding test on 2 strains was reported as part of test 1. It is not reported whether plate incorporation procedure or pre incubation procedure was used.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (μg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>	> 1000			

Test 1	> 1000	≥ 1000	negative
Test 2	> 1000	≥ 1000	negative
<i>Present</i>	> 1000		
Test 1	> 1000	≥ 1000	negative
Test 2	> 1000	≥ 1000	negative

Remarks - Results

In both mutation assays, there was no reduction of the bacterial background lawn and no biologically relevant decrease in the number of revertants at any of the concentrations tested in all tester strains in the absence and presence of S9-mix.

In both mutation assays, no increase in the number of revertants was observed upon treatment with the test substance under all conditions tested.

The negative and strain-specific positive control values were within laboratory historical control data range indicating that the test conditions were adequate and that the metabolic activation system functioned properly.

CONCLUSION

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

TEST FACILITY

Notox B.V. (2009b)

B.3. Genotoxicity – bacteria

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 440/2008 B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure (preliminary test)/Pre incubation procedure (main test)

Species/Strain

S. typhimurium: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA⁻

Metabolic Activation System

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

Concentration Range in Main Test

a) With metabolic activation: 0, 50, 150, 500, 1500, 5000 µg/plate
b) Without metabolic activation: 0, 50, 150, 500, 1500, 5000 µg/plate

Vehicle

Acetone

Remarks - Method

No deviation from the protocol.

RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>				
Test	> 5000	> 5000	≥ 500	negative
<i>Present</i>				
Test	> 5000	> 5000	≥ 500	negative

Remarks - Results

The test substance caused no visible reduction in the growth of the bacterial background lawn at any dose levels and was, therefore, tested up to the maximum recommended dose level of 5000 µg/plate. A blue colour was noted from 50 µg/plate with an associated, particulate precipitate observed 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 bacterial strains, at any dose level either with or without metabolic activation or exposure method.

All of the positive 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 (2011)

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