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

PUBLIC REPORT

Polymer in Liquitint Blue 452 and R452

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 CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1647	Milliken Design Inc	Polymer in Liquitint Blue 452 and R452	ND*	≤10 tonnes per annum	Component of household laundry detergents

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

The environmental hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	Hazard statement
Acute Aquatic Toxicity (Category 2)	H401 - Toxic to aquatic life

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 PEC/PNEC ratio 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

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified polymer as introduced:
 - Loading operation to be carried out under a fume extractor.
 - Blending in a closed mixing tank under local exhaust ventilation.
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced, and as an ingredient in laundry detergents:
 - Avoid skin and eye contact
 - Avoid generation of aerosols
 - Clean up spills promptly
- 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, and during reformulation and packaging processes:
 - Eye protection
 - Gloves and coveralls

- Respiratory protection if dusts or aerosols may 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 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 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;
 - further data on the genotoxicity potential of the notified polymer becomes available. or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of consumer laundry detergents, 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 (M)SDS of the products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Milliken Design Inc (ABN: 58 142 096 759)
7/860 Doncaster Road
DONCASTER EAST VIC 3109

NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn \geq 1000 Da (Similar to chemical previously assessed by NICNAS).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, other names, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:
Most physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Liquitint Blue 452 or R452 (products containing the notified polymer)

MOLECULAR WEIGHT

>1,000 Da

ANALYTICAL DATA

Reference GPC and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >98%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa:

Property	Value	Data Source/Justification
Melting Point/Freezing Point	<0 °C	(M)SDS
Boiling Point	119 °C at 101.3 kPa	Measured
Density	1,100 kg/m ³	(M)SDS
Vapour Pressure	Not determined	Expected to be low due to high Mw >1000
Water Solubility	> 200 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	> 1 year at 25 °C, pH 4, 7 t _{1/2} = 177 days at 25 °C, pH 9	Measured
Partition Coefficient (n-octanol/water)	log Pow = -0.767 at 20 °C	Measured
Adsorption/Desorption	Not determined	Based on its cationic properties, the notified polymer is expected to predominantly adsorb to soil or

Dissociation Constant	Not determined	sediments. The notified polymer is a salt and will be ionised under environmental conditions
Flash Point	150 °C at 101 kPa	Measured (study report not provided)
Flammability limits	Not determined	Not expected to form flammable mixtures in air, based on low vapour pressure
Autoignition Temperature	Not determined	
Explosive Properties	Not determined	Does not contain explosives
Oxidising Properties	Not determined	Not expected to oxidise based on structure

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 cannot be classified 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 a solution in products at 70% or 72.7% concentration.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	<10	<10	<10	<10	<10

PORT OF ENTRY

Melbourne and Sydney

IDENTITY OF RECIPIENTS

Milliken Design Inc

TRANSPORTATION AND PACKAGING

The notified polymer will be transported by road. The notified polymer will be transported in the original import containers (20 L pails and 215kg HDPE drums) until formulated into end-use products.

USE

The notified polymer will be used as a colorant in domestic laundry detergents (powder and liquid).

OPERATION DESCRIPTION

Reformulation

Containers of the notified polymer will not be opened or repackaged prior to reformulation into domestic laundry detergents. Warehouse workers will pump the notified polymer into closed storage tanks. The notified polymer will be transferred manually to a closed blending tank under local exhaust ventilation or pumped automatically via a metering system. After blending into laundry detergents, the end-use products containing up to 0.5% of the notified polymer will be transferred via automatic filling machines into appropriate containers for distribution to retail outlets.

End-Use

Consumers will open the laundry product containers (containing $\leq 0.5\%$ of the notified polymer) and manually measure out the required volume of the product (typically 50 mL or 50 g). The product will be measured using the cap of the container or into a plastic measuring/dispensing cup before adding to the washing machine. After the washing process the consumers will remove washed clothes from the machine. At this stage the notified polymer will be almost completely rinsed from the clothes.

The laundry detergent may also be used in hand-washing of clothes.

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>
Transportation/warehousing (12-20)	16	20
Warehouse workers (6-10)	1	20
Blending operators (10)	8	50
Laundry workers (>1,000)	8	220

EXPOSURE DETAILS

Transportation and Storage

Worker exposure to the notified polymer during the importation, transport and storage of the notified polymer and products containing it is not expected, except in the event of an accident where packaging may be breached.

Reformulation

Warehouse and blending workers may experience dermal and ocular exposure to the notified polymer at up to 72.7% from spills and splashes while opening the imported containers, transfer of the contents, manual blending and filling the packages or liquid or powder laundry detergent. Workers involved in cleaning and maintenance may experience dermal and ocular exposure.

Inhalation exposure during formulation of liquid laundry detergents is expected to be low due to the high molecular weight and subsequent formulation into an aqueous mixture, unless aerosols are generated during processing. During formulation of powder laundry detergents, inhalation exposure to the polymer at up to 0.5% is possible if the dusts are generated from the powder.

Exposure to the notified polymer is expected to be minimised through the use of enclosed and automated processes during transfer and blending of the notified polymer where possible. Reformulation is expected to be done a room temperature, however extra ventilation can be used if higher temperatures are needed. Exposure to the notified polymer is expected to be further minimised through the use of personal protective equipment (PPE) including coverall, protective gloves and goggles.

6.1.2. Public Exposure

End-Use

The notified polymer will be available to the public as an ingredient in laundry detergents. Consumers may experience incidental dermal or ocular exposure to the notified polymer at $\leq 0.5\%$ through the use of laundry products in washing machines. Inhalation exposure is not expected during domestic use of laundry detergents. The use of PPE such as protective gloves is likely to be highly variable between consumers.

If hand-washing of clothes is carried out using the laundry detergent, there may be dermal exposure to the diluted detergent containing low levels of the notified polymer ($< 0.005\%$).

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer and a suitable analogue of the notified polymer (previously assessed by NICNAS) are summarised in the following table. For full details of the studies on mutagenicity and genotoxicity, refer to Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Acute oral toxicity (rat)*	LD50 > 5000 mg
Skin irritation (rabbit)*	Slightly irritating
Eye irritation (rabbit)*	Not irritating
Mutagenicity – bacterial reverse mutation	Mutagenic in TA98 +S9 only
Genotoxicity – in vitro micronucleus test (cultured human lymphocytes)	non genotoxic
Genotoxicity – in vivo micronucleus test (rat bone marrow)	non genotoxic

*Study carried out on analogue (previously assessed polymer).

Toxicokinetics, metabolism and distribution.

No toxicokinetic data on the notified polymer was submitted. Absorption through the skin and gastrointestinal (GI) tract is expected to be limited by the high MW > 1000 . The low vapour pressure indicates that the notified polymer is not likely to be inhaled as a vapour.

Acute toxicity

The analogue polymer has low acute oral toxicity ($LD_{50} > 5000$ mg/kg bw in rats). There is no data available on the acute dermal or inhalation toxicity of the notified polymer.

Irritation and Sensitisation

In studies in rabbits, the analogue polymer was slightly irritating to the skin and non-irritating to the eyes. No data is available regarding the skin sensitisation of the notified polymer. The notified polymer does not include a structural alert for sensitisation.

Mutagenicity/Genotoxicity.

In a bacterial reverse mutation assay, the notified polymer was mutagenic to one of the bacterial strains tested (*Salmonella typhimurium* strain TA98) in the presence of S-9 only. The notified polymer did not induce micronuclei in cultured human peripheral blood lymphocytes treated *in vitro*, nor was it clastogenic in an *in vivo* bone marrow micronuclei test in mice. It is noted that the *in vivo* study could only be carried out at low concentrations, with a maximum dose of 25 mg/kg, because of toxicity of the notified polymer to the test animals after intraperitoneal injection.

The significance of the positive result in the bacterial reverse mutation study is not clear. Additional information e.g., an *in vivo* mutation assay in transgenic mice, would be needed to clarify the genotoxic potential of the notified polymer.

Health hazard classification

Based on the limited toxicity data available, the notified polymer cannot be classified 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**

Based on the available information, the notified polymer is likely to be a slight skin irritant. The results of genotoxicity studies on the notified polymer were mixed, with one positive result in a bacterial reverse mutation study. The significance of the positive result is not clear, and further data would be needed to clarify the polymer's genotoxicity potential.

The highest potential for dermal, ocular and inhalation exposure is for workers weighing and reformulating the notified polymer as imported at $\leq 72.7\%$. However, the loading operation is carried out under a fume extractor and blending occurs in a closed mixing tank under local exhaust ventilation. Furthermore, use of personal protective equipment such as coveralls, respirator, gloves and eye protection should minimise exposure to the notified chemical.

Contact with the notified polymer at up to 0.5% in formulated laundry detergents may also occur during filling of the consumer packages, transport, and handling of the products at retail outlets. It is expected that contact would occur only in the event of a leak or spill, in which case standard clean up procedures would ensue with the appropriate personal protective equipment to clean the spill.

Overall, on the basis of the engineering controls, safe work practices and personal protective equipment (and low concentration of the notified polymer in the end-use product), occupational exposure to the notified polymer is expected to be low and the risk to the health of workers from use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health

There is the potential for low level incidental dermal or ocular exposure of the public to the notified polymer at up to 0.5%, during use of household powder and liquid laundry products in washing machines, as well as dermal exposure to much lower concentrations (estimated 0.005%) during hand-washing of laundry. PPE (gloves) may or may not be worn by consumers; however, it is expected that consumers would wash off any spilt material from their skin.

Overall the exposure of the public is expected to be low, and the risk to the public is not considered unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The imported notified polymer will be reformulated locally into final products for use in consumer laundry detergents. It is estimated that up to 1% of total import volume of the notified polymer may be released to sewer as trade waste from the cleaning of equipment and small spills during reformulation processes. Accidental spills and leaks during transport, blending and handling are expected to be collected using adsorbent material and be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified polymer is proposed to be used primarily as a colourant in household laundry detergents. As such, it is expected that effectively the entire quantity of imported notified polymer will be disposed of to the sewer after use, apart from the very small quantity that remains on fabric articles which will eventually be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer will be disposed of to the sewer after use. A very small proportion of the total imported quantity is expected to be disposed of to landfill, as residues in containers or on fabric articles at the end of their useful life, or from spills or leaks.

7.1.2. Environmental Fate

Due to its cationic nature, notified polymer discharged to sewer is expected to be efficiently removed in the sludge at the sewage treatment plants. Sewage sludge will be disposed of to landfill or used in soil remediation. Notified polymer disposed of to landfill is expected to associate with negatively charged humic material and consequently be effectively immobilised.

The notified polymer is hydrolytically stable at low pH ($t_{1/2} > 1$ year at 25 °C, pH 4 and 7) while it slowly degrades at higher pH ($t_{1/2} = 177$ days at 25 °C, pH 9). The notified polymer is not expected to bioaccumulate based on its low water/n-octanol partition coefficient ($\log Pow = -0.767$) and high molecular weight. In landfill and soil, the notified polymer is expected to finally degrade via biotic or abiotic pathways to form water vapour, oxides of carbon and nitrogen and inorganic salts.

1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated assuming for the worst case, 100% release of the notified polymer into sewer. A removal rate of 90% is used according to Boethling and Nabholz (1997) for cationic polymers of high molecular weight (> 1000).

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.4	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	Mitigation
Daily effluent production:	4,523	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	0.61	µg/L
PEC - Ocean:	0.06	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 54.521 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 0.363 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 1.815 mg/kg and 3.63 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 0.606 µg/L may potentially result in a soil concentration of approximately 4.04 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 20.19 µg/kg and 40.39 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer (daphnia) or close analogue (fish and algae) are summarised in the table below. Details of these studies can be found in Appendix C.

The notified polymer is structurally similar to the analogue and there is not expected to be significant difference between the polymers in physical-chemical properties and ecotoxicity. Therefore, it is considered to be scientifically reasonable to predict the ecotoxicity endpoints for fish and algae using the analogue data.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
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Fish Toxicity	96 h LC50 = 390 mg/L*	Not harmful to fish
Daphnia Toxicity	48 h EC50 = 47 mg/L**	Harmful to aquatic invertebrates
Algal Toxicity	EC50 = 1.7 mg/L*	Toxic to algae

* Measured data determined for the analogue

** Measured data determined for the notified polymer

The notified polymer is not acutely harmful to fish but is harmful to daphnia and toxic to algae. Based on the acute toxicity endpoint for algae, the notified polymer is formally classified as “Acute Category 2: Toxic to aquatic life” under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009). The notified polymer is not expected to be bioaccumulative given its low log Pow and high molecular weight. Therefore, the notified polymer is not classified for its long-term hazard to aquatic life.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) was calculated using the acute toxicity endpoint of the notified polymer to alga. A conservative safety factor of 1000 was used as only one endpoint was available for the notified polymer

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment

EC50 (Alga).	1.7	mg/L
Assessment Factor	1000	
PNEC:	1.7	µg/L

7.3. Environmental Risk Assessment

<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC µg/L</i>	
Q - River:	0.61	1.7	0.356
Q □ Ocean:	□.06	1.7	0.036

The calculated Risk Quotient (PEC/PNEC) was < 1 for both river and ocean water systems, indicating that the notified polymer is not expected to pose an unreasonable risk to the environment on the basis of its assessed use pattern and maximum annual importation volume.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Boiling Point** 119 °C at 101.3 kPa

Method In-house method
 Remarks Summary only provided
 Test Facility Milliken (2013)

Water Solubility > 200 g/L at 20 °C

Method In house method in accordance to OECD TG 105 Water Solubility.
 Remarks Flask Method. Only study summary was provided. A total of 0.46 ml of water was added to 0.1 g of test substance. The mixture was shaken for 10 minutes and visually checked for any undissolved substance. The test substance was visually determined to be soluble in 0.46 ml of water at room temperature.
 Test Facility Milliken (2013)

Hydrolysis as a Function of pH

Method OECD TG 111 Hydrolysis as a Function of pH.

<i>pH</i>	<i>T (°C)</i>	<i>t</i> _{1/2}
4	25	> 1 years
7	25	> 1 years
9	25	177 days

Remarks At pH 4 and 7, less than 10% hydrolysis were observed when the test solutions were incubated at 50 °C for 5 days in the preliminary test, equivalent to the half-life of greater than 1 year. No further test was required as per test guideline requirement. A full tier test was conducted at pH 9.0 according to the test guideline without significant deviation from the protocol.
 Test Facility Milliken (2012)

Partition Coefficient (n-octanol/water) log Pow = -0.767 at 20 °C

Method In house method in accordance to OECD TG 107 Partition Coefficient (n-octanol/water).
 Remarks Flask Method. Only study summary was provided. Test substance (1 g) was dissolved into 50 g of water. The solution was transferred to three different volume separatory funnels, followed with the addition of 50 g of octanol and thorough shaking. The mixtures were allowed to settle overnight to allow the test substance to separate into two phases. The concentrations of test substance in each phase were determined by spectrophotometric method.
 Test Facility Milliken (2013)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Genotoxicity – bacteria**

TEST SUBSTANCE	Notified polymer (72.7%)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	Aroclor 1254-induced rat liver post-mitochondrial fraction
Concentration Range in	a) With metabolic activation: 20-5000 µg/plate
Main Test	b) Without metabolic activation: 20-5000 µg/plate
Vehicle	Purified water
Remarks - Method	Dosages were adjusted to account for the concentration of the notified polymer in the test substance.

A preliminary test was performed to determine the toxicity of the test material (TA100 only) in the presence of S-9. These data were considered acceptable for mutation assessment and are presented in the report as TA100 mutagenicity data for Experiment 1.

Vehicle and positive controls were used in parallel with the test material, for all strains in both experiments. Positive controls: i) without S-9: 2-nitrofluorene (TA98), sodium azide (TA100, TA1535), 9-aminoacridine (TA1537), mitomycin C (TA102); ii) with S9: benzo[a]pyrene (TA98), 2-aminoanthracene (TA100, TA1535, TA1537, TA102).

RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
Absent	≥ 1000			
Test 1		>1000	>5000	No
Test 2		>800	>5000	No
Present				
Test 1		>1000	>5000	Yes
Test 2		>800	>5000	Yes

Remarks - Results

In both Test 1 and 2, there were statistically significant increases in revertant numbers at 1000 µg/plate and above in experiment 1 and 800µg/plate and above in Experiment 2 in TA98 in the presence of S-9.

Statistically significant increases in revertant numbers were observed in Experiment 1 in TA98 and TA102 in the absence of S9, and TA1537. These increases were not reproduced in Experiment 2 and were therefore not considered to be indicative of mutagenic activity. The number of revertants in these strains were less than double that of the negative controls.

No significant increases in revertants were not seen in any other test groups.

The positive and negative controls gave satisfactory responses, confirming the validity of the test system.

CONCLUSION

The notified polymer was mutagenic to bacteria in *Salmonella typhimurium* strain TA98 in the presence of S-9 only, under the conditions of the test.

TEST FACILITY Covance Laboratories Ltd (2010)

B.2. Genotoxicity – in vitro

TEST SUBSTANCE Notified Polymer (72.7%)

METHOD OECD TG 487 Draft guideline for In vitro Mammalian Cell Micronucleus Test.

Species/Strain Human

Cell Type/Cell Line Lymphocyte cells

Metabolic Activation System S-9 Aroclor 1254

Vehicle Purified water

Remarks - Method The test method used by notifier is in line with the OECD test guideline.

The negative control was sterile purified water. The positive controls used were mitomycin C, cyclophosphamide and vinblastine.

A correction factor of 1.376 was applied to all concentrations to account for the purity value of 72.7%.

Metabolic Activation	Test Substance Concentration ($\mu\text{g/mL}$)	Exposure Period	Harvest Time
Absent			
Test 1	10, 20*, 40*, 60, 80*, 100, 120, 140*, 160, 180, 200, 250	3	24
Test 2	5, 10*, 20, 30*, 40, 50*, 60*, 70, 80, 90, 100, 120	24	24
Present			
Test 1	50, 100*, 125*, 150*, 175, 200, 225, 250, 275, 300, 350, 400	3	24

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	Test Substance Concentration ($\mu\text{g/mL}$) Resulting in:			
	Cytotoxicity in Preliminary Test (>60%)	Cytotoxicity in Main Test (>60%)	Precipitation	Genotoxic Effect
Absent				
Test 1	≥ 233	≥ 160	>250	Negative
Test 2	≥ 84	≥ 60	>400	Negative
Present				
Test 1	≥ 389	≥ 175	>120	Negative
Test 2				

Remarks - Results

Statistically significant increases in the number of MNBN (micronucleated binucleate) cells were seen at the highest concentration tested following 3+21 hour and 24+0 hour treatments, in the absence of metabolic activation. These increases were discounted because they only occurred in one of two replicate cultures.

No statistically significant increases in the number of MNBN cells were seen in other test groups

CONCLUSION

The notified polymer did not induce micronuclei in cultured human peripheral blood lymphocytes treated *in vitro* under the conditions of the test.

TEST FACILITY

Covance Laboratories Ltd (2010)

B.3. Genotoxicity – in vivo

TEST SUBSTANCE	Notified Polymer (72.7%)
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Han Wistar rats
Route of Administration	Intraperitoneal injection
Vehicle	Sterile purified water
Remarks - Method	Dosages were chosen on the basis of a range-finding experiment. The negative control was sterile purified water and the positive control was Cyclophosphamide (CPA).

The test article was given two administrations, 24 hours apart and animals were sampled 24 hours after the final administration, thus enabling examination of cells exposed to the test article over a period of 24 to 48 hours prior to sampling.

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Sacrifice Time hours</i>
I (vehicle control)	6M	0	48
II (low dose)	6M	6	48
III (mid dose)	6M	12.5	48
IV (high dose)	6M	25	48
V (positive control, CPA)	6M	20	48

CPA=cyclophosphamide

RESULTS

Doses Producing Toxicity	In the range-finding study the test substance administered intraperitoneally at 100, 500 and 2000 mg/kg resulted in the death of all animals within 30 minutes of administration. Male animals dosed at 50 mg/kg/day displayed moderate to severe clinical signs of toxicity which included decreased activity, hypothermia, hunched posture and laboured breathing.
Genotoxic Effects	In the main study using dosages up to 25 mg/kg, no clinical signs or change in the PCE/NPCE ratio were noted. However discoloured urine was noted on Day 2 at the highest dose level, indicating systemic exposure to the coloured test substance. The test substance did not induce a statistically significant increase in micronuclei in the polychromatic erythrocytes of the bone marrow of male rats treated up to 25 mg/kg/day. Significant heterogeneity of the results was seen in the control and low dose group results, however this was not considered to affect the validity of the results..
Remarks - Results	The positive control gave a satisfactory response and the negative controls were comparable with historical data, confirming the validity of the test system.
CONCLUSION	The notified polymer was not clastogenic under the conditions of this <i>in vivo</i> bone marrow micronuclei test.
TEST FACILITY	Covance Laboratories Ltd (2010)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue
METHOD	US EPA 797.1400 Fish acute toxicity – Flow through.
Species	Rainbow trout (<i>Oncorhynchus mykiss</i>)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not available
Remarks – Method	The controls were clear throughout the test, while all the test concentrations were dark blue colour and increased in darkness with concentration. All test chambers were free of precipitate and surface film during the study.
	Due to the concentration of the dye in the test chambers it was not possible to observe the fish. Therefore, fish were randomly netted and held near the surface to determine behaviour. For this reason, accurate biological observations of sublethal effects could not be made until the end of the study when fish were placed in clear water.
RESULTS	
LC50	390 mg/L at 96 hours (95% confidence limit, 217-442 mg/L).
NOEC	109 mg/L at 96 hours.
Remarks – Results	At concentrations up to and including 109 mg/L, all fish were all assumed normal throughout the test and found to be normal at 96 hours, except one fish at 33.0 mg/L and 96 hours which displayed a loss of equilibrium. Effects after 48 hours were noted in test concentrations higher than 109 mg/L. At 271 mg/L, 7 fish were observed surfacing and displaying laboured respiration. However, at 96 hours all fish bar one (which displayed dark discolouration) were found to be normal in this test concentration.
	Fish deaths were observed in the 442 mg/L test concentration (maximum concentration tested), with 6 at 72 hours and another 7 at 96 hours (cumulative total of 13). Only one fish was observed as normal at 96 hours, with the remaining six displaying surfacing behaviour, loss of equilibrium and/or quiescence.
CONCLUSION	The analogue and, by inference, the notified polymer are not harmful to fish
TEST FACILITY	ABC Laboratories (1996a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Product containing the notified polymer
METHOD	OECD TG 202 <i>Daphnia</i> sp. Acute Immobilisation Test - Static.
Species	<i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg CaCO ₃ /L
Analytical Monitoring	Spectrophotometry
Remarks - Method	Based on the results from the preliminary range-finding test, 20 daphnids (2 replicates of 10 animals) were exposed to the test media under static conditions for 48 hours in the definitive test. The test was performed

according to the test guideline above without significant deviation from the protocol.

RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h [acute]	48 h [acute]
Control	N/A	20	0	0
10	9.88*	20	0	0
18	N/A	20	0	0
32	N/A	20	0	0
56	N/A	20	2	16
100	101*	20	0	20

Measured concentration at the exposure time of 48 hours

EC50 47 mg/L at 48 hours (95% confidence limits of 43-53 mg/L)
 NOEC 32 mg/L at 48 hours
 Remarks - Results Concentrations of the test substance were determined for the test media at the nominal concentrations of 10 and 100 mg/L at 0 and 48 hours. The measured concentrations were close to the nominal concentrations and the ecotoxicity endpoints were therefore reported based on the nominal test concentration.
 All validity criteria for the test were satisfied.

CONCLUSION The notified polymer is harmful to aquatic invertebrates

TEST FACILITY Harlan (2011)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Analogue

METHOD US EPA 797.1050 Alga, Growth Inhibition Test.
 Species Algae (*Selenastrum capricornutum*)
 Exposure Period 96 hours
 Concentration Range Actual: control, 0.12, 0.24, 0.45, 0.87, 1.8 and 3.7 mg/L
 Auxiliary Solvent None
 Water Hardness N/A
 Remarks - Method The 0.45, 0.87, 1.8 and 3.7 mg/L test solutions were observed to be purple in colour with no visible precipitate, with colour intensity increasing with the increase in test concentrations. The 0.12 and 0.24 mg/L test solutions, and control were observed not to have a purple colour

RESULTS

Biomass		Growth	
E_bC50 mg/L at 96 h	NOE_bC mg/L	E_rC50 mg/L at 96h	NOE_rC mg/L
N/A	N/A	1.7	0.45
(95% confidence 1.5 -1.9 mg/L)			

Remarks - Results Cell counts were conducted at 24, 48, 72 and 96 hours for each replicate of the control and each test concentration. The multiple means test showed a significant inhibition effect ($p > 0.05$) on growth in the 0.87, 1.8 and 3.7 mg/L test concentrations as compared to the control. The 96 hour EC_{10} and EC_{90} were calculated to be 0.30 mg/L (95% confidence limits = 0.19 and 0.41 mg/L) and greater than 3.7 mg/L, respectively.

The test material is a dye and all solutions above 0.24 mg/L were purple

in colour, a primary factor in the inhibition of the growth of the algae is the reduction of available light. The notifier has not performed a modified growth inhibition test to differentiate between a reduced growth of algae due to real toxic effects of the notified polymer on the algal cells, or due to an indirect effect, a reduced algal growth by light absorption in coloured test solutions. As deleterious effects can be caused by the interception of light (shading effect) necessary for algal growth, the authors claim that the toxicity observed may have been due to physical factors rather than chemical.

CONCLUSION

The analogue and, by inference, the notified polymer are toxic to algae

TEST FACILITY

ABC Laboratories (1996b)

BIBLIOGRAPHY

- Boethling RS & Nabholz JV (1997) Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton JD & Sutcliffe R, ed. Ecological Assessment of Polymers; Strategies for product stewardship and regulatory programs. New York, Van Nostrand Reinhold, pp 187–234.
- ABC Laboratories (1996a) Acute Flow-Through Toxicity of Experimental 9881-33 to Rainbow Trout (*Oncorhynchus mykiss*) (Study No. 43069, 1996), Missouri USA, ABC Laboratories Inc. (Unpublished report submitted in the thirty party notification).
- ABC Laboratories (1996b) Acute Toxicity of Experimental 9881-33 to *Selenastrum capricornutum* Printz (Study No. 43070, 1996), Missouri, USA, ABC Laboratories Inc. (Unpublished report submitted in the third party notification).
- Harlan (2011) Acute toxicity of *Daphnia magna* (Study No. 41103648, December 2011). Derbyshire, UK, Harlan laboratories Ltd, Milliken Chemical. (Unpublished report submitted by the notifier).
- Milliken (2012) Liquitint Blue 452: Hydrolysis as a function of pH (OECD 111) (Study No. RV20120613A and RV20120717A, July 2012), Spartanburg, USA, Milliken. (Unpublished report submitted by the notifier).
- Milliken (2013) Evaluation of the partition coefficient, water solubility and boiling point of Liquitint Blue 452 (February, 2013), Spartanburg, USA, Milliken & Company. (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.
- NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia
- SWA (2012) Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, <http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/spray-painting-and-powder-coating>.
- SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, <http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace>.
- 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 >.