File No: LTD/1642

January 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Fluid 22260 VP

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/1642	Wacker Chemie AG	Polymer in Fluid 22260 VP	ND*	≤5 tonnes per annum	Antifoaming agent for the paper industry

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment
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 and limited release to surface waters, 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 engineering controls to minimise occupational exposure to the notified polymer (as introduced):
  - Enclosed, automated processes, where possible

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure when handling the notified polymer (as introduced):
  - Avoid contact with skin and eyes

- 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):
  - Gloves
  - Goggles
  - Coveralls

  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;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from an antifoaming agent for the paper industry, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 5 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 (M)SDS of a product containing the notified polymer provided by the notifier was 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)
Wacker Chemie AG (ABN: 11 607 113 062)
1/35 Dunlop Road
MULGRAVE VIC 3170

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constitutents, residual monomers, impurities, additives/adjuvants, use details, import volume and identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints (excluding water solubility).

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2008)
China (2009)
USA (2009)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Fluid 22260 VP (Contains the notified polymer at <80% concentration)
Pulpsil 235 C (Contains the notified polymer at ≤4% concentration)
Pulpsil 238 C (Contains the notified polymer at ≤4% concentration)

MOLECULAR WEIGHT
>1,000 Da

ANALYTICAL DATA
Reference NMR, IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >70%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Brown coloured liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Introduced as an aqueous dispersion
Boiling Point	Not determined	Introduced as an aqueous dispersion
Density	1010 kg/m^3 at 25 °C*	(M)SDS
Vapour Pressure	0.037 kPa at 150 °C *	(M)SDS
Water Solubility	Water dispersible	Measured
Hydrolysis as a Function of pH	Not determined	Not expected to hydrolyse under environmental conditions (pH 4-9)
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is surface active and will tend to accumulate at the

		phase interface of octanol and water.
Adsorption/Desorption	Not determined	Expected to partition to surfaces from water in the environment based on its surface activity.
Dissociation Constant	Not determined	Not expected to ionise under environmental conditions (pH 4-9)
Flash Point	>110 °C at 101.3 kPa*	(M)SDS
Flammability	Not expected to be flammable	Based on flashpoint
Autoignition Temperature	375 °C*	(M)SDS
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

*Fluid 22260 VP containing <80% notified polymer

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

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported into Australia as a component (≤4%) of an aqueous dispersion.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-5	1-5	1-5	1-5	1-5

PORT OF ENTRY
Melbourne (by sea)

IDENTITY OF MANUFACTURER/RECIPIENTS
Wacker Chemie AG (and other recipients throughout Australia)

TRANSPORTATION AND PACKAGING
Products containing the notified polymer (at ≤4% concentration) will be imported in 200 kg steel drums or 950 kg polyethylene intermediate bulk containers (IBCs) and transported by road for distribution to the end users across Australia.

USE
Antifoaming agent used in the manufacture of paper and paperboard. The manufactured paper and paperboard may be used in a variety of applications, including food contact applications.

OPERATION DESCRIPTION
At reformulation sites, the imported product containing the notified polymer (at ≤4% concentration) will be charged, under vacuum, into a sealed, stainless steel processing vessel and blended with other ingredients. The reformulated product containing <0.5% notified polymer will then be drummed out via a dedicated spear into IBCs.

At pulp processing plants, the reformulated product (<0.5% notified polymer) will be added, via sealed/automated dosing, at various stages of the chemical pulping process (including washing, screening and bleaching stages) at a rate of ≤0.1 kg/tonne of pulp. The manufactured paper/paperboard will contain <1 ppm

notified polymer.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS
Waterside, storage and transport workers may come into contact with the product containing the notified polymer, only in the unlikely event of an accident.

At reformulation and end-use sites, workers may be exposed to the notified polymer (at ≤4% concentration) via the dermal (and perhaps ocular) route during transfer processes, quality control analysis and cleaning and maintenance tasks (inhalation exposure is not expected). The potential for exposure of workers to the notified polymer is expected to be minimised through the use of enclosed, automated processes and personal protective equipment (PPE; e.g. gloves, goggles and protective clothing).

Incidental exposure to manufactured paper/paperboard containing residual notified polymer (<1 ppm) may also occur.

6.1.2. Public Exposure
The antifoaming products containing the notified polymer (at ≤4% concentration) are intended for use in industrial settings only. The public may have incidental exposure to residual notified polymer (<1 ppm) in the manufactured paper/paperboard (including through the use in food contact applications). The potential for migration of the notified polymer from the paper/paperboard (e.g. into foodstuffs) may be minimised by the presence of coatings on these items.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Assessment Conclusion*
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration	non genotoxic
Genotoxicity – in vitro mammalian cell gene mutation	non genotoxic

Based on the surfactant nature of the notified polymer, absorption across the gastrointestinal tract and dermal absorption may occur. However, the extent of absorption is likely to be limited by the high molecular weight of the notified polymer (>1000 Da; only a small proportion of low molecular weight species <1000 Da).

The notified polymer was found to be non-mutagenic in a bacterial reverse mutation assay and was not clastogenic in *in vitro* mammalian chromosome aberration and mammalian cell gene mutation assays, under the conditions of the tests. While no further toxicity studies on the notified polymer were provided, the potential for adverse effects is likely to be reduced by the high molecular weight of the notified polymer. However, based on the presence of a reactive functional group in the notified polymer and the presence of a proportion of low molecular weight species, the potential for adverse effects cannot be ruled out.

Health hazard classification
Based on the available information, the notified polymer is not recommended for classification 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
Exposure of workers to the notified polymer (at ≤4% concentration) may occur during reformulation and pulp processing operations. Based on the presence of a reactive functional group in the notified polymer and a proportion of low molecular weight species, the potential for adverse effects cannot be ruled out. Therefore,

measures to minimise exposure of workers to the notified polymer (as imported) should be implemented. Such measures include the use of enclosed/automated processes (where possible) and the wearing of PPE by workers. Based on the information available, adverse effects are not expected following incidental exposure to the notified polymer from the manufactured paper/paperboard.

Under the proposed usage conditions, the risk of the notified polymer to workers is not considered to be unreasonable.

6.3.2. Public Health

While the notified polymer is intended for use in industrial settings only, the public may have incidental exposure to residual notified polymer (<1 ppm) in the manufactured paper/paperboard (including through the use in food contact applications).

The potential for migration of the residual notified polymer is expected to be minimised by the presence of coatings on the manufactured paper and the high molecular weight of the notified polymer. The potential for absorption of any residual migrated polymer is also expected to be limited by the high molecular weight of the polymer. Furthermore, the concentration of residual notified polymer in the manufactured paper/paperboard is very low (<1ppm). Based on the information available, adverse effects are not expected following incidental exposure to the notified polymer from the manufactured paper/paperboard. Therefore, when used in the proposed manner, the risk to public health 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 not be manufactured in Australia. Blending of the notified polymer will occur on-site. In the event of an accidental spill during transport or blending, the notified polymer is expected to be absorbed with inert material and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified polymer will be added during the paper making process as a defoaming agent. Release of the notified polymer during use is expected to be limited. The paper plant processing systems will be closed, continuous processes. However, up to 45% of the notified polymer may adhere to the paper pulp during processing. At the end of its usefulness, the solution containing the remainder of the notified polymer (up to 55%) will be evaporated and the notified polymer will be oxidised. The resulting dry silica product is expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Paper to which the notified polymer is adhered, is likely to be disposed of to landfill (50%) and recycled (50%). Empty packaging containing residues of the notified polymer is expected to be recycled, where the notified polymer will be washed into an effluent system with water. Waste streams containing the notified polymer are expected to undergo waste water treatment before release to sewer. Residues in empty packages are expected to account for 0.8 kg of the notified polymer per annum.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified polymer, which is adhered to paper fibres or is part of oxidised waste from reformulation, is expected to be disposed of to landfill. In landfill, the notified polymer is not expected to be bioavailable or mobile based on its high molecular weight and surface activity. Notified polymer that is released to sewer or waste water treatment is expected to be efficiently removed during waste water treatment plant (WWTP) and sewage treatment plant (STP) processes. At least 90% of the notified polymer is expected to be removed based on its high molecular weight and surface activity. Notified polymer that enters surface waters is not expected to cross biological membranes based on its high molecular weight and is therefore not expected to bioaccumulate. The notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon, nitrogen and silicon.

7.1.3. Predicted Environmental Concentration (PEC)

A predicted environmental concentration (PEC) for the notified polymer was calculated and is outlined in the

table below. The notifier expects that up to 45% of the total import volume of the notified polymer (2250 kg) is expected to sorb to the paper surface during paper manufacture. Approximately 50% of the paper to which the notified polymer is adhered is expected to be recycled and the notified polymer released to sewer. Based on the high molecular weight and surface active properties, the notified polymer is expected to be efficiently removed during STP processes. Removal in STPs is expected to be at least 90%.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	<2250	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	<1125	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	4.33	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	
Daily effluent production:	4523	ML
Dilution Factor - River	1	
Dilution Factor - Ocean	10	
PEC - River:	0.10	µg/L
PEC - Ocean:	0.01	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 8.61 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/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified polymer may approximate 0.0570 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 0.285 mg/kg and 0.570 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/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/m^3). Using these assumptions, irrigation with a concentration of 0.096 µg/L may potentially result in a soil concentration of approximately 0.638 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 3.19 µg/kg and 6.38 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicological data were submitted. Polymers without significant ionic functionality are generally of low concern to the aquatic environment. The notified polymer is expected to be efficiently removed during STP processes and therefore limited release to the aquatic environment is expected. Based on its assumed low hazard, the notified polymer is not expected to be released in ecotoxicologically significant concentrations and is therefore not expected to pose an unreasonable risk to aquatic life.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) for the notified polymer has not been calculated as no ecotoxicological data for the polymer are available.

7.3. Environmental Risk Assessment

The majority of the notified polymer is expected to be disposed of to landfill or, notified polymer released to sewer, is expected to be efficiently removed during WWTP and STP processes. Based on the assessed use pattern, the notified polymer is expected to have limited release to the aquatic compartment and it is not expected to be released to surface waters in ecotoxicologically significant concentrations. The notified polymer is also expected to remain in landfill. Therefore, the notified polymer is not expected to pose an unreasonable risk to the environment based on the assessed use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility Dispersible

Method	Modified EC Council Regulation No 440/2008 A.20 Solution/Extraction Behaviour of Polymers in Water.
Remarks	After 24 hours of stirring, gravimetric analysis was used to determine the insoluble fraction of the test substance. The solubility of the test substance was calculated to be 2.6 g/L at pH 5. The solution after filtration was reported to be white and cloudy.
Test Facility	Wacker (2008)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	Phenobarbitone/β-naphthoflavone-induced rat liver (S9 homogenate)
Concentration Range in Main Test	a) With metabolic activation: 0-5000 µg/plate b) Without metabolic activation: 0-5000 µg/plate
Vehicle	Ethanol
Remarks - Method	A preliminary toxicity test (0-5000 µg/plate) was performed to determine the toxicity of the test material (TA98 and TA100 only). Vehicle and positive controls were used in parallel with the test material. Positive controls: i) without S9: sodium azide (TA100, TA1535), 4-nitro-o-phenylenediamine (TA98, TA1537) and methyl methane sulfonate (TA102); ii) with S9: 2-aminoanthracene (TA98, TA100, TA102, TA1535, TA1537).

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	≥2500	>5000	Negative
Test 2		≥1580	>5000	Negative
Present				
Test 1	>5000	≥5000	>5000	Negative
Test 2		≥5000	>5000	Negative

Remarks - Results	No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains up to and including the maximum dose, either with or without metabolic activation. The positive controls gave satisfactory responses, confirming the validity of the test system.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BSL (2008a)

B.2. Genotoxicity – in vitro

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Chinese hamster
Cell Type/Cell Line	Chinese hamster V79
Metabolic Activation System	Phenobarbitone/β-naphthoflavone-induced rat liver (S9 homogenate)
Vehicle	Cell culture medium
Remarks - Method	A preliminary toxicity test (0-5000 µg/mL; 4 hour exposure with and without metabolic activation) was performed to determine the toxicity of the test material. Vehicle and positive controls (ethylmethanesulfonate without S9 and

cyclophosphamide with S9) were used in parallel with the test material.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	125*, 250*, 500*, 750, 1000*, 2500	4 hours	24 hours
Test 2	1.95, 3.9, 7.8*, 15.6*, 31.3*, 62.5*, 125*, 250*, 500*	20 hours	20 hours
Present			
Test 1	62.5, 125, 250, 300, 350, 400, 450, 500*, 1581*, 5000*	4 hours	24 hours
Test 2	187.5, 375*, 750*, 1000*, 2000*, 5000*	4 hours	24 hours

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥500	≥250	≥125	Negative
Test 2		≥31.3	≥31.3	Negative
Present				
Test 1	≥500	≥1581	≥62.5	Negative
Test 2		≥750	≥187.5	Negative

Remarks - Results

No statistically significant increase in the number of cells with aberrations was noted at any concentration, with and without metabolic activation.

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

CONCLUSION

The notified polymer was not clastogenic to Chinese hamster V79 cells treated in vitro under the conditions of the test.

TEST FACILITY

BSL (2008b)

B.3. Genotoxicity – in vitro

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.

Species/Strain: Mouse

Cell Type/Cell Line: Mouse lymphoma L5178Y

Metabolic Activation System: Phenobarbitone/β-naphthoflavone-induced rat liver (S9 homogenate)

Vehicle: Cell culture medium

Remarks - Method

A preliminary toxicity test (0-5000 µg/mL: 4 hour exposure with and without metabolic activation; 0-2500 µg/mL: 24 hour exposure without metabolic activation) was performed to determine the toxicity of the test material.

Vehicle and positive controls (ethylmethanesulfonate and methylmethanesulfonate without S9 and benzo[a]pyrene with S9) were used in parallel with the test material.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	20*, 78*, 156*, 313*, 625*, 1250*, 2000*, 2500*	4 hours	72 hours	11-14 days
Test 2	0.5*, 1*, 2*, 5*, 10*, 20*, 60*, 100*	24 hours	48 hours	11-14 days

Present				
Test 1	39*, 78*, 156*, 313*, 625*, 1250*, 2000*, 2500*	4 hours	72 hours	11-14 days
Test 2	25*, 200*, 400*, 900*, 1500*, 1750*, 2000*, 2500*	4 hours	72 hours	11-14 days

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥156	≥156	≥20	Negative
Test 2	≥400	≥1	≥20	Negative
Present				
Test 1	≥156	≥156	≥20	Negative
Test 2		≥400	≥25	Negative

Remarks - Results

In the presence of metabolic activation (test 1), the relative mutation factor at the highest concentration tested (2500 µg/mL) was 1.97, with a corresponding relative total growth of 17.02% (colony sizing indicated a large/small colonies quotient of 1.55). In test 2 (with metabolic activation), the highest relative mutation factor obtained was 1.54 at 2000 µg/mL (no apparent dose-response relationship was evident; large/small colonies quotient of <1 at 1750-2500 µg/mL). The study authors noted that the number of mutants was within the historical control range for the laboratory.

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

CONCLUSION

The notified polymer was not clastogenic to mouse lymphoma L5178Y cells treated in vitro under the conditions of the test.

TEST FACILITY

BSL (2008c)

BIBLIOGRAPHY

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BSL (2008b) In vitro Mammalian Chromosome Aberration Test in Chinese Hamster V79 Cells with [notified polymer] (Study No. 083267, December, 2008). Planegg, Germany, BSL Bioservice Scientific Laboratories GmbH (Unpublished report submitted by the notifier).

BSL (2008c) In vitro Mammalian Cell Gene Mutation Assay (Thymidine Kinase Locus/$TK^{+/-}$) in Mouse Lymphoma L5178Y Cells with [notified polymer] (Study No. 083266, December, 2008). Planegg, Germany, BSL Bioservice Scientific Laboratories GmbH (Unpublished report submitted by the notifier).

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Wacker (2008) Bestimmung der Löslichkeit von [notified polymer] in vollentsalztem Wasser und in einer Mischung aus 50 Vol-% Ethanol/50 Vol-% vollensalstes Wasser (Study No. Not reported, April, 2008) Test location not provided, Germany, Wacker Chemie (unpublished report provided by the notifier).