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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Rayoflex Series, Solarflex FSP Series and Suncure FLM Series Inks

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Energy.

This Public Report is 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/2044	DIC Australia Pty Ltd	Polymer in Rayoflex series, Solarflex FSP series and Suncure FLM series inks	ND*	< 1 tonne per annum	Component of UV-curable industrial printing inks

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As only limited toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

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 assumed low hazard, 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 in ink products:
  - Local exhaust ventilation and adequate general 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 in ink products:
  - Avoid contact with skin and eyes
  - Avoid breathing in aerosols

- 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 when transferring the inks to printers, maintaining printing equipment and cleaning up any spills:
  - Protective clothing
  - Gloves
  - Goggles

  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 of 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

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

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 chemical 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 importation volume exceeds one tonne per annum notified polymer;
  - the notified polymer is intended to be used in applications with direct food contact;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from component of UV-curable industrial printing inks, 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.

Safety Data Sheet
The SDS of the notified polymer (and products containing the notified polymer) provided by the notifier were reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
DIC Australia Pty Ltd (ABN: 12 000 079 550)
323 Chisholm Road
AUBURN NSW 2144

NOTIFICATION CATEGORY
Limited-small volume: Synthetic polymer with Mn < 1000 (1 tonne or less per year)

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, chemical constituents, residual reactants, 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 for all physical and chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2007)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymer in Rayoflex series, Solarflex FSP series and Suncure FLM series inks

MOLECULAR WEIGHT
Number average molecular weight (Mn) < 1,000 g/mol

ANALYTICAL DATA
Reference IR, HPLC, NMR and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Freezing Point*	- 9.5 °C	Measured
Boiling Point	Estimated to be high	Modelled (US EPA, 2012)
Density	1,000 kg/m^3 at 20 °C	Estimated
Vapour Pressure	< 0.001 kPa at 20 °C	Estimated
Water Solubility	Immiscible, estimated as 9.7×10^{-9} g/L	Modelled (US EPA, 2012)
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities, but not expected to hydrolyse due to water immiscibility
Partition Coefficient (n-octanol/water)	Log P_{ow} = 7.59	Modelled (US EPA, 2012)
Adsorption/Desorption	Log K_{oc} = 5.07 (MCI method) Log K_{oc} = 4.72 (log P_{ow} method)	Modelled (US EPA, 2012)

Property	Value	Data Source/Justification
Dissociation Constant	Not determined	Not expected to ionise in the environmental pH range of 4-9.
Flash Point	> 93 °C	Estimated
Flammability	Not determined	-
Autoignition Temperature	Not determined	-
Explosive Properties	No explosive properties	Statement provided by the notifier (Chemicalia, 2018)
Oxidising Properties	No oxidising properties	Statement provided by the notifier (Chemicalia, 2018)

* No study details provided

DISCUSSION OF PROPERTIES
Measurements of partition coefficient (n-octanol/water) and adsorption/desorption were attempted in accordance with OECD Test Guidelines 107 and 106 respectively; however, the tests could not be performed due to extremely low water solubility of the notified polymer.

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

Physical hazard classification
Based on the limited physico-chemical data depicted in the above table, the notified polymer cannot be recommended for hazard classification according to the *Globally Harmonised System of 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 not be manufactured, reformulated or repackaged in Australia. The notified polymer will be imported in various finished low migration UV-curable ink products at ≤ 5% concentration. The ink products will include Rayoflex series, Solarflex FSP series and Suncure FLM series.

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

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

PORT OF ENTRY
Sydney, Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
DIC Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The ink products containing the notified polymer will be transported in their original import containers, which will be 10 kg plastic tubs for the Rayoflex series, 5 kg plastic tubs for the Solarflex FSP series and 3 kg plastic tubs for the Suncure FLM series. All ink products containing the notified polymer will be transported by road to be stored in the notifier's warehouses, and then delivered to respective printing companies throughout Australia.

USE
The notified polymer will be used as a component of UV-curable printing inks (at ≤ 5% concentration) for flexographic or lithographic printing processes on various substrates including paper, carton boards, foil boards, selected plastics and other non-absorbent substrates. The inks containing the notified polymer may potentially be used to print on substrates used in the food industry. The notifier stated that prints with the cured inks will not be in direct contact with food.

OPERATION DESCRIPTION
The UV-curable low migration inks containing the notified polymer will be used for commercial printing. Most of these processes are expected to be automated, but certain tasks require manual operations by professional workers. During printing, printer operators will pour the inks from plastic tubs into the ink reservoirs on the

printing equipment and monitor the substrates from any problems. The printing inks may be sampled by the quality control (QC) staff during the printing processes. After UV-curing, the notified polymer will be chemically bonded with other ink components to form an inert solid matrix bound onto the substrates, and not expected to be available for release. Residue inks on the equipment will be cleaned by rags and solvents, and collected for disposal.

The UV-curable inks containing the notified polymer will be used on different substrates with different printing equipment. The Rayoflex series are UV-curable flexographic low migration inks used for printing on primed aluminium foil. The Solarflex FSP series are UV-curable flexographic low migration inks used for printing on substrates applicable for food or pharmaceutical packaging. The Suncure FLM series are UV-curable lithographic low migration inks used for printing on non-food contact substrates or outer food packaging.

Although some of the printing inks containing the notified polymer will be printed on substrates used in the food or pharmaceutical industry, the notifier has indicated that the cured inks will not be in direct contact with food or pharmaceutical products.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	4 – 8	50
QC chemists/technical staff	0.5 – 6	25
Printer operators	1 – 2	25
Service technicians	8	200

EXPOSURE DETAILS

Transport and Storage
Transport and storage workers may come into contact with the notified polymer (at ≤ 5% concentration) only in the unlikely event of an accident when the packaging of the imported ink products is breached.

End use
Dermal or possibly incidental ocular exposure to the notified polymer at ≤ 5% concentration may occur during certain stages of the printing operations, such as transferring the inks from ink containers to printers. Exposure can be minimised by safe work practices, such as the use of barrier creams and PPE including impervious gloves, goggles and protective clothing, when handling the ink products. Inhalation exposure to the notified polymer at ≤ 5% may also occur due to the possible release of ink aerosols from the printers. However, this is expected to be minimised by the use of local ventilation during the printing process. Incidental dermal and ocular exposure will also be possible during equipment maintenance that may be minimised through the proposed use of barrier creams and appropriate PPE.

Once the ink is cured by UV, the notified polymer will be chemically reacted with other ink ingredients and bound to the matrix of the substrates and is not expected to be available for exposure.

6.1.2. Public Exposure
The UV-curable printing inks containing the notified polymer will not be made available to the general public. Therefore, direct public exposure to the notified polymer is not expected.

Members of the public may come into contact with printed materials. However, once the ink is cured, the notified polymer will be reacted and bound to the matrix of the substrates and is not expected to be available for exposure.

Although some of the printing inks containing the notified polymer will be printed on substrates used in the food and pharmaceutical industry, the notifier has indicated that the cured inks will not be in direct contact with food or pharmaceutical products. The inks containing the notified polymer will be mainly used on the outer surface of

the packaging. In case that the ink is printed on the inner surface of packaging, additional lamination with sealing film will be carried out to prevent the ink ingredients from migrating into food or pharmaceutical products.

6.2. Human Health Effects Assessment

The results from three genotoxicity studies conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix A.

Endpoint	*Result and Assessment Conclusion*
Mutagenicity – bacterial reverse mutation	may cause mutagenic effects with metabolic activation
Genotoxicity – *in vitro* mammalian chromosome aberration test	non genotoxic
Genotoxicity – *in vitro* mammalian cell gene mutation test	non mutagenic

Toxicokinetics, metabolism and distribution

No information on the toxicokinetics, metabolism and distribution of the notified polymer was provided. Based on the molecular weight (< 1,000 g/mol) of the notified polymer, there is potential for the polymer to cross biological membranes. However, absorption of the notified polymer is expected to be limited based on the relatively low water solubility (9.7×10^{-9} g/L) with a calculated log P_{ow} of 7.59.

Mutagenicity/Genotoxicity

Three studies on the genotoxicity of the notified polymer were provided.

Positive results were observed in an *in vitro* bacterial reverse mutation test on one strain of *Salmonella typhimurium* with metabolic activation. A 4 – 7 fold dose dependent increase in the number of revertant colonies was recorded for *S. typhimurium* strain TA1535. The positive results were repeated with metabolic activation in subsequent tests. However, in the absence of metabolic activation, no dose dependent increase of revertant colonies was observed.

In an *in vitro* mammalian cell chromosome aberration test and in an *in vitro* mammalian cell gene mutation test, the notified polymer did not induce an increase in the number of cells with chromosome aberrations and did not induce gene mutations in mammalian cells with or without metabolic activation. The notified polymer is not clastogenic or mutagenic under the conditions of these tests.

As the notified polymer tested positive in the bacterial reverse mutation assay with metabolic activation, in the absence of *in vivo* genotoxicity study data, the potential for genotoxicity of the notified polymer cannot be ruled out.

No other toxicity data on the notified polymer were provided.

Health hazard classification

As only limited toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The potential for the notified polymer to cause genotoxic effects cannot be completely ruled out. Workers may come into contact with the notified polymer at a concentration ≤ 5% in UV curable printing inks. Given the low use concentration of the notified polymer and the enclosed nature of the ink containers and reservoirs in the printers, exposure to the notified polymer is expected to be infrequent or incidental. Exposure potential may further be reduced by following the safe use instructions and using appropriate PPE during service, cleaning up spills and printing activities.

As there is no information provided on irritation and sensitisation properties of the notified polymer, safe work practices such as avoiding skin and eye contact should be observed to avoid potential dermal and ocular exposure.

Once the inks are cured, the notified polymer will be chemically reacted with other ink ingredients and bound to the matrix of the substrates and is not expected to be available for exposure.

Overall, based on the limited exposure and expected low dermal absorption potential of the notified polymer, the risk to workers is not considered to be unreasonable.

6.3.2. Public Health

The printing inks containing the notified polymer will not be available for use to the general public, but the public may come into contact with printed substrates. Some of the printed substrates will be used in food or pharmaceutical industry. The European Printing Ink Trade Association (EuPIA) has listed the notified polymer in the Suitability List of Photo-initiators for Low Migration UV Printing Inks and Varnishes specifically for use on non-contact side of food packaging. The notifier has stated that the imported ink products containing the notified polymer will not be used in a manner with potential direct food contact.

Once cured, the notified polymer is expected to be chemically reacted with other ink ingredients and bound to the matrix of the substrates, and will not be available for exposure.

Therefore, based on the proposed use patterns, 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 as a component of finished UV-curable ink products. Accidental spills of the notified polymer during import, transport or storage are expected to be adsorbed onto a suitable material and collected for disposal, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The notified polymer will be used as a component of UV-curable printing inks for commercial flexographic or lithographic printing processes on various substrates including paper, carton boards, foil boards, selected plastics and other non-absorbent substrates. Most of these printing processes are expected to be automated. After UV-curing, the notified polymer will be bound onto the substrate matrix, and not be available for release. Residue ink on the equipment will be cleaned by rags and solvents, and collected for disposal, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the notified polymer is expected to share the fate of the printed substrates to which it has been applied, either subjected to substrate recycling processes, or being disposed of to landfill at the end of their useful lives. As estimated by the notifier, printing on paper accounts for approximately 50% of the import volume of the notified polymer. A recent Australian waste report states an average paper recycling rate of 60% (Blue Environment Ltd., 2016). In the worst case scenario, up to 60% of the notified polymer used on paper which is equivalent to 30% of the annual import volume of the notified polymer, could be released to the aquatic environment from paper recycling processes.

The notifier estimates that empty ink containers will contain residues of the notified polymer up to 1% of the import volume. These containers will be collected for recycling by an approved waste management facility, or be disposed of to landfill, in accordance with local government regulations.

7.1.2. Environmental Fate

As a result of its use pattern, most of the notified polymer is expected to share the fate of the substrates to which it has been applied, either subjected to substrate recycling processes, or being disposed of to landfill at the end of their useful lives. Waste plastic items may be recycled, but eventually plastic items containing the notified polymer will be disposed of to landfill. In landfill, the notified polymer will be present as cured solids and will be neither bioavailable nor mobile.

The notified polymer is not expected to partition significantly to the air compartment and is not expected to persist in the air, as the half-life of the notified polymer in air is calculated to be < 3 h, based on reactions with hydroxyl radicals (US EPA, 2012; calculated using AOPWIN v1.92).

During paper recycling processes, waste paper is repulped using a variety of chemical treatments which, amongst other things, enhance ink detachment from the fibres. Waste water from paper recycling processes containing the notified polymer is expected to be treated at an onsite wastewater treatment plant before potential release to sewers or surface waters. Based on its predicted high log P_{ow} and its immiscibility in water, the notified polymer is expected to associate with sludge at wastewater treatment plant. The waste sludge containing the notified polymer will be sent to landfill for disposal or to agricultural land for remediation. The notified polymer is expected to bind to soil or sludge based on its predicted high log K_{oc} and immiscibility in water. In landfill, soil, sludge and water, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume 50% of the import volume of the notified polymer will be used on paper substrate and 60% of this would be potentially released to sewers through paper recycling processes (Blue Environment Ltd., 2016). As paper recycling occurs at facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume. It is also assumed under the worst-case scenario that there is no removal of the notified polymer during wastewater treatment processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	30	%
Annual quantity of chemical released to sewer	300	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1.15	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0	%
Daily effluent production:	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.24	µg/L
PEC - Ocean:	0.02	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 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 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.24 µg/L may potentially result in a soil concentration of approximately 1.58 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymer in the applied soil in 5 and 10 years may be approximately 7.89 µg/kg and 15.78 µg/kg, respectively.

7.2. Environmental Effects Assessment

No measured ecotoxicity data were submitted. The ecotoxicity effects of the notified polymer were predicted using ecological structure activity relationship (ECOSAR v2.0, US EPA, 2016). The results indicate that the notified polymer is not harmful to fish, aquatic invertebrates and algae up to its water solubility limit. The ECOSAR estimation procedure used here is a standard approach, and is considered reliable to provide general indications of the likely environmental effects of the polymer. However, this method is not considered sufficient to formally classify the hazards of the notified polymer to aquatic life under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated as the notified polymer is not considered likely to be harmful to aquatic organisms up to its water solubility limit.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified polymer has not been calculated as the notified polymer is not considered to be harmful to aquatic organisms up to its water solubility limit. Therefore, based on the assumed low hazard, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test EC Commission Regulation 440/2008 B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria
Species/Strain	*Salmonella typhimurium*: TA1535, TA1537, TA98, TA100 *Escherichia coli*: WP2uvrA
Metabolic Activation System	S9 mix from phenobarbital (PB)/β-naphthoflavone (NF) induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 3 – 5,000 µg/plate b) Without metabolic activation: 3 – 5,000 µg/plate
Vehicle	DMSO
Remarks - Method	GLP statement of compliance was provided. No significant protocol deviations were noted. Negative and positive controls were run concurrently with the notified polymer.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in*		
	Cytotoxicity	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	> 5,000	≥ 1,000	Negative
Test 2	> 5,000	≥ 1,000	Negative
Present			
Test 1	> 5,000	≥ 3,330	Positive*
Test 2	> 5,000	≥ 1,660	Positive*

* Only observed in TA1535.

Remarks - Results	In the presence of metabolic activation, the TA1535 strain showed a 4 – 7 fold dose dependent increase in the number of revertant colonies. In the absence of metabolic activation, no dose dependent increase of revertant colonies was observed. All other tested strains did not show any dose dependent increase of revertant colonies. Negative and positive controls were within the laboratory historical control data range (except for the WP_2uvrA strain without metabolic activation which gave a positive result above the range limit in the negative control). This indicated that the test conditions were adequate and the metabolic activation system functioned properly.
CONCLUSION	The notified polymer was mutagenic to bacteria treated *in vitro* with metabolic activation under the conditions of the test.
TEST FACILITY	NOTOX (2011a)

A.2. Genotoxicity – *in vitro* mammalian chromosome aberration test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test EC Directive 2000/32/EC B.10 Mutagenicity - *In vitro* Mammalian Chromosome Aberration Test
Species/Strain	Human blood cells

Cell Type/Cell Line	Lymphocyte
Metabolic Activation System	S9 mix from phenobarbital (PB)/β-naphthoflavone (NF) induced rat liver
Vehicle	DMSO
Remarks - Method	GLP statement of compliance

A dose range-finding study was carried out at 1 – 333 µg/mL. The dose selection for the main experiments was based on toxicity observed in the range-finding study and solubility test.

Vehicle and two positive controls (mitomycin C and cyclophosphamide) were run concurrently with the notified polymer.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	10*, 33*, 100*	3 h	24 h
Test 2	1, 3, 10*, 30, 50, 70*, 100*	24 h	24 h
Test 3	1*, 3, 10, 20*, 30, 40*, 50, 70, 100	48 h	48 h
Present			
Test 1	10*, 33*, 100*	3 h	24 h
Test 2	10*, 30*, 100*	3 h	48 h

*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	≥ 33	> 100	≥ 100	Negative
Test 2		≥ 100	≥ 70	Negative
Test 3		≥ 30	≥ 70	Negative
Present				
Test 1	> 100	> 100	≥ 100	Negative
Test 2		> 100	≥ 100	Negative

Remarks - Results

In the absence or presence of S9 mix, the notified polymer did not induce a statistically significant increase in the number of cells with chromosome aberrations.

In one experiment, the notified polymer increased the number of cells with endoredupliated chromosomes in the absence of S9 mix after exposure for 24 h. However, this increase was not observed in the experiments conducted at 3 h and 48 h of exposure time. The study authors considered this increase to be not biologically relevant.

Negative and positive controls were within the laboratory historical control data range. This indicated that the test conditions were adequate and the metabolic activation system functioned properly.

CONCLUSION

The notified polymer was not clastogenic to human lymphocytes treated *in vitro* under the conditions of the test.

TEST FACILITY

NOTOX (2011b)

A.3. Genotoxicity – *in vitro* mammalian cell gene mutation test

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 476 *In vitro* Mammalian Cell Gene Mutation Test
EC Directive 2000/32/EC B.17 Mutagenicity - *In vitro* Mammalian Cell Gene Mutation Test

Species/Strain	Mouse
Cell Type/Cell Line	L5178Y Mouse lymphoma cells ($TK^{+/-}$-3.7.2C)
Metabolic Activation System	S9 mix from phenobarbital (PB)/β-naphthoflavone (NF) induced rat liver
Vehicle	DMSO
Remarks - Method	GLP statement of compliance was provided. Dose range-finding studies were carried out at 3 – 333 µg/mL with 3 h and 24 h of exposure. The dose selection for the main experiments was based on toxicity observed in the range-finding study and the solubility test. Negative and two positive controls (methyl methanesulfonate and cyclophosphamide) were run concurrently with the notified polymer.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*
Absent			
Test 1	0.03, 0.1, 0.3, 1, 3, 10, 33, 100	3 h	2 days
Test 2	0.03, 0.1, 0.3, 1, 3, 10, 33, 100	24 h	2 days
Present			
Test 1	0.03, 0.1, 0.3, 1, 3, 10, 33, 100	3 h	2 days
Test 2	0.03, 0.1, 0.3, 1, 3, 10, 33, 100	3 h	2 days

All cultures were selected for mutation frequency (MF) 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	> 333	> 100	≥ 100	Negative
Test 2	≥ 333	> 100	≥ 100	Negative
Present				
Test 1	> 333	> 100	≥ 100	Negative
Test 2		> 100	≥ 100	Negative

Remarks - Results	The notified polymer did not lead to a statistically significant increase in the number of mutation frequencies at the TK-locus, either in the presence or absence of metabolic activation. The number of small and large colonies in treated cultures was within the range of the concurrent vehicle control and the historical negative control data. The increase in the frequencies of mutant colonies induced by the positive control demonstrated the sensitivity of the test method and the metabolic activity of the S9 mix
CONCLUSION	The notified polymer was not mutagenic to mouse lymphoma cells treated *in vitro* under the conditions of the test.
TEST FACILITY	NOTOX (2011c)

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