File No.: LTD/2106

November 2019

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Z-192

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/2106	Lubrizol International Inc	Z-192	ND*	≤ 80 tonnes per annum	Component of industrial printing inks and coatings

* Not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the limited available information, 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
Based on the assumed low hazard and reported 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 engineering controls to minimise occupational exposure during reformulation and use of the notified polymer:
  - Enclosed/automated processes if possible
  - 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 reformulation and use of the notified polymer:
  - Avoid contact with skin and eyes
  - Avoid inhalation of 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:
  - Impervious gloves
  - Protective clothing
  - Eye protection
  - Respiratory protection if inhalation exposure may occur

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.

- A copy of the 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.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

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.

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 g/mol;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from component of industrial printing inks and coatings, 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 provided by the notifier was 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)
Lubrizol International Inc (ABN: 52073495603)
28 River Street
SILVERWATER NSW 2128

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 g/mol

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details exempt from publication include: chemical name, other names, CAS number, 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)
Schedule data requirements are varied for hydrolysis as a function of pH and dissociation constant.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2018)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Z-192

MOLECULAR WEIGHT
Number average molecular weight (Mn) is > 1,000 g/mol.

ANALYTICAL DATA
Reference NMR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
100%

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	*Value*	*Data Source/Justification*
Melting Point	18 ± 3 °C	Measured
Boiling Point	Decomposes above 280 °C	Measured
Density	1,130 kg/m^3 at 20 °C	Measured
Vapour Pressure	4.63 × 10^{-5} kPa at 25 °C	Measured
Water Solubility	1.52 × 10^{-3} g TOC/L 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities but unlikely to undergo significant hydrolysis under environmental conditions (pH 4- 9).
Partition Coefficient (n-octanol/water)	log Pow > 10 at 20 °C	Measured
Adsorption/Desorption	log K_{oc} > 5.63	QSAR
Dissociation Constant	Not determined	Polymer is expected to remain ionised under environmental conditions

Property	*Value*	*Data Source/Justification*
Flash Point	188 °C	Measured
Autoignition Temperature	Not determined	-
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties

DISCUSSION OF PROPERTIES
For 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 is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

The notified polymer has a flash point of 188 ºC which is greater than 93 °C. Based on *Australian Standard AS1940* definitions for combustible liquid, the notified polymer may be considered as a Class C2 combustible liquid if the polymer has a fire point below the boiling point.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. It will be imported into Australia in neat form and as products containing the notified polymer at < 10% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0 – 20	10 – 30	20 – 40	30 – 75	40 – 80

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Not identified

TRANSPORTATION AND PACKAGING
The notified polymer in neat form will be imported in 20 kg or 180 kg steel drums. Reformulated products containing the notified polymer will be transported in 20 L pails and 200 L HDPE drums. These containers will be delivered to warehouses for storage.

USE
The notified polymer will be used at < 10% concentration as an additive in UV-cured coatings and printing inks to improve pigment dispersion and stability.

OPERATION DESCRIPTION

Reformulation
At the reformulation site, the notified polymer in neat form will be weighed or directly metered from the drums into a stainless steel blending tank. It will be mixed with UV-curable monomers, pigments and other additives to produce the final formulation. After the blending is completed, the product containing the notified polymer at < 10% concentration will be transferred for quality control testing, and then gravity fed into containers through for distribution.

End Use
The notified polymer at < 10% concentration will be a component of printing inks and coating products for industrial use. Products containing the notified polymer will be manually poured or pumped into the reservoirs of the application equipment. Ink products will be predominantly applied using industry standard printing methods, and coating products will be applied by brush, roller or spray. After application, the substrate will be cured by exposure to UV light. The process is expected to be fully automated. Residues of inks and coatings in the container will be washed and collected or sent to licenced drum recyclers.

The notified chemical will be applied on substrates including metal, wood and paper. It is estimated that 45% of the import quantity will be used on metal and 10% on wood for coating use, and 45% will be used as printing inks on paper.

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 workers	2 – 3	10 – 15
Reformulation workers	8	50
Laboratory	1	20
Application workers	4	260

EXPOSURE DETAILS

Transport and Storage
Transport and storage workers may come into contact with the notified polymer in neat form (as imported) or at 10% concentration (in end use products) only in the unlikely event of accidental breaching of containers.

Reformulation
At reformulation sites, dermal and ocular exposure to the notified polymer in neat form may occur when weighing and transferring the notified polymer in liquid form to the blending tank or during equipment cleaning and maintenance. Inhalation exposure is not expected unless aerosols are generated during reformulation. According to the SDS provided, exposure to the notified polymer during reformulation will be minimised through the use of good general ventilation and personal protective equipment (PPE). This may include gloves, safety goggles, coveralls, and respiratory protection if ventilation is inadequate.

End use
At end use sites, dermal, ocular and inhalation exposure to paints and coatings containing the notified polymer at < 10% concentration may occur during transfer, application and cleaning processes. Application will be carried out only at industrial sites, and is expected to use an automated process, once the reservoirs for the equipment have been charged with ink or coatings. The potential for exposure during the manual processes are expected to be minimised through the use of PPE, including coveralls, gloves and goggles, as well as appropriate respiratory protection where ventilation is inadequate or during spray application.

Once dried and cured, the notified polymer will be bound within a solid matrix and is not expected to be available for exposure.

6.1.2. Public Exposure
The inks and coatings containing the notified polymer at < 10% concentration will be used in industrial settings only and will not be made available to the public. Once the coating and inks have been dried and cured, the notified polymer will be bound into an inert solid matrix and will be unavailable for exposure.

6.2. Human Health Effects Assessment
No toxicity data were submitted for the notified polymer. Several endpoints were assessed using information on an analogue polymer having a similar structure, but higher molecular weight and containing lower levels of low

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

Endpoint	*Result and Assessment Conclusion*
Acute oral toxicity – rat	LD50 > 2,000 mg/kg bw; low toxicity
Skin irritation – rabbit	Slightly irritating
Eye irritation – rabbit	Slightly irritating
Skin sensitisation – guinea pig, Buehler Test	No evidence of sensitisation
Mutagenicity – bacterial reverse mutation	Non mutagenic

Toxicokinetics, Metabolism and Distribution
No data on toxicokinetics for the notified polymer was provided. For dermal absorption, molecular weights below 100 g/mol are favourable for absorption and molecular weights above 500 g/mol do not favour absorption (ECHA, 2017). Dermal uptake is likely to be low to moderate if the water solubility is between 1-100 mg/L and moderate to high if the water solubility is between 100-10,000 mg/L (ECHA, 2017). Based on the high molecular weight (> 1,000 g/mol), low water solubility (1.52 mg/L) and partition coefficient (log Pow > 10) of the notified polymer, absorption across biological membranes is unlikely to occur.

Acute Toxicity
No data were submitted on acute oral, dermal and inhalation toxicity of the notified polymer. An analogue polymer was found to have low acute oral toxicity in rats.

Irritation and Sensitisation
The analogue polymer was slightly irritating to the skin and eyes of rabbits.

The analogue polymer was not a skin sensitiser in guinea pigs in a Buehler test.

Repeated dose toxicity
No repeated dose toxicity studies were provided for the notified polymer or any analogues.

Mutagenicity/Genotoxicity
The analogue polymer was not mutagenic in a bacterial reverse mutation assay.

Health Hazard Classification
Based on the limited available information, 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
The notified polymer contains structural alerts for corrosion/irritation. Tests on an analogue polymer indicated that it is a slight skin and eye irritant. However, the notified polymer may have increased irritation potential, as it is of lower molecular weight, and has a higher level of low molecular weight species, compared to the analogue polymer

6.3.1. Occupational Health and Safety

Reformulation
During reformulation workers may come into contact with the notified polymer in neat form during transfer, maintenance, and cleaning operations. Control measures indicated on the SDS for the notified polymer include use of adequate general ventilation and suitable PPE such as gloves, eye and face protection and long sleeve shirts, to minimise worker exposure.

End-use
During end-use, professional workers may come into contact with the notified polymer at < 10% concentration during transfer, application and cleaning processes. At this concentration, any irritation effects are expected to be reduced. Exposure and risk would be further mitigated by use of control measures such as ventilation and PPE, as indicated on the SDS provided.

Overall, based on the information on the analogue polymer and the occupational settings and controls described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health

Products containing the notified polymer will not be available to the public. Members of the public may come into contact with articles coated with finished coating products containing the notified polymer at < 10% concentration. However, the notified polymer in cured coatings and inks is expected to be bound with the inert matrix and will not be available for exposure.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

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. Reformulation is expected to occur at ink manufacturing sites. Release may occur from accidental spills from the manual transfer into blending tanks and storage drums. Any accidental spills are to be either recycled or collected using absorbent material and subsequently disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified polymer is expected to be cured into the coating matrix after application onto the substrate. Excess wastes are expected to account for 2% of the total import volume, in addition a further 2% of import volume is expected to be generated from the cleaning of application equipment. Wastes generated are expected to be collected, cured and eventually disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer is expected to share the fate of the substrate it is applied to. It is estimated that 45% of the notified polymer will be used on metal substrates which are expected to be either recycled or disposed of to landfill. Another 10% of the notified polymer is to be used as a coating on wooden substrates which are expected to be disposed of to landfill. The remaining 45% of the import volume is to be used as a printing ink on paper substrates. According to the recent Australian National Waste Report (Blue Environment Ltd., 2016), 60% of the waste paper treated with the notified polymer is expected to be recycled domestically, with the remaining 40% disposed of to landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified polymer. Most of the notified polymer is expected to share the fate of the substrate to which it is applied, to be disposed of to landfill in the case of metal and wood substrates, as well as 40% of paper substrates. The notified polymer disposed of to landfill is not expected to be mobile based on its potential cationic properties and high molecular weight. According to the recent Australian National Waste Report (Blue Environment Ltd., 2016), 60% of the waste paper treated with the notified polymer is expected to be recycled domestically. During recycling processes, waste paper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks and coatings from the fibres. The notified polymer discharged to wastewater from paper recycling processes is expected to be effectively removed through adsorption to sludge or by flocculation at wastewater treatment plants (Boethling and Nabholz, 1997; Guiney et al., 1997).

Sludge containing the notified polymer will be sent to landfill for disposal or agricultural land for remediation. The notified polymer will be bound to soil or sludge due to its cationic functionality and is not expected to be mobile in the environment (Boethling and Nabholz, 1997). The notified polymer is not expected to be bioaccumulated in aquatic life given its high molecular weight. The notified polymer is expected to undergo degradation by biotic and abiotic processes, eventually forming water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

A predicted environmental concentration (PEC) worst case scenario has been calculated. It was assumed that 27% (60% of the volume used in printing inks) of the annual import quantity of the notified polymer is released to the sewer from whatever scenario over 260 days/year, with no removal of the notified polymer by sewage treatment plant (STP) processes. Taking a worst-case scenario, the extent to which the notified polymer is removed from the effluent in STP processes based on the properties of the notified polymer has not been considered.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	80,000	kg/year
Proportion expected to be released to sewer	27%	
Annual quantity of chemical released to sewer	21,600	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	83.08	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:	17.03	µg/L
PEC - Ocean:	1.70	µg/L

7.2. Environmental Effects Assessment

No ecotoxicity data were provided for the notified polymer. The notified polymer contains cationic functionality with a Functional Group Equivalent Weight (FGEW) < 5000, and is therefore potentially harmful to aquatic organisms in environmental water. However, due to the low water solubility, this effect is not expected to be significant. This is supported by the study results (studies not evaluated and summarised) on an analogue of the notified polymer, which indicated that it is at most harmful to aquatic life (96 h LC50 fish, 43 mg/L and 72 h EC50 algae, > 100 mg/L).

7.2.1. Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) was not calculated as no ecotoxicologial endpoints were determined.

7.3. Environmental Risk Assessment

On the basis of the use pattern and likely low hazard, it is unlikely the notified polymer will reach ecotoxicologially significant concentrations. Therefore, the notified polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Freezing Point 18 ± 3 °C

Method	OECD TG 102 Melting Point/Melting Range (1995) EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature
Remarks	A pour point procedure was used.
Test Facility	Envigo (2019a)

Boiling Point Decomposes at > 280 °C without boiling

Method	OECD TG 103 Boiling Point (1995) EC Council Regulation No 440/2008 A.2 Boiling Temperature
Remarks	Differential scanning calorimetry (DSC) was used. The mean onset of decomposition was 280 °C.
Test Facility	Envigo (2019a)

Density 1,130 kg/m^3 at 20 ± 0.5 °C

Method	OECD TG 109 Density of Liquids and Solids (2012) EC Council Regulation No 440/2008 A.3 Relative Density
Remarks	The pycnometer method was used.
Test Facility	Envigo (2019a)

Vapour Pressure 4.63×10^{-5} kPa at 25 °C

Method	OECD TG 104 Vapour Pressure (2006) EC Council Regulation No 440/2008 A.4 Vapour Pressure
Remarks	A vapour pressure balance was used.
Test Facility	Covance (2019a)

Water Solubility 1.52×10^{-3} g TOC/L at 20 °C

Method	OECD TG 105 Water Solubility
Remarks	Flask Method
Test Facility	Envigo (2019a)

Partition Coefficient (n-octanol/water) log Pow > 10 at 20 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	HPLC Method. The following deviations from the OECD test guidelines were noted: a 20% water mobile phase was used instead of 25% and the pH was 3 instead of the typical pH range of 5-9. This is not expected to influence the overall validity of the test.
Test Facility	Envigo (2019a)

Flash Point 188 ± 2 °C at 102.3 kPa

Method	EC Council Regulation No 440/2008 A.9 Flash Point
Remarks	A Pensky-Marten closed cup apparatus procedure was used.
Test Facility	Kindlow (2017)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute Oral Toxicity – Rat

TEST SUBSTANCE	Analogue polymer
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test (1987) EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test
Species/Strain	Rat/Sprague-Dawley CD strain
Vehicle	Arachis oil BP
Remarks – Method	GLP Certificate. No protocol deviations. Dosage for the main test was determined in a range-finding study.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	10 (5F, 5M)	2,000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity	No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks – Results	The animals showed expected body weight gain over the observation period.

CONCLUSION	The analogue polymer is of low acute toxicity via the oral route.
TEST FACILITY	Safepharm (1997a)

B.2. Skin Irritation – Rabbit

TEST SUBSTANCE	Analogue polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion (1992) EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation)
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 M
Vehicle	None.
Observation Period	7 days
Type of Dressing	Semi-occlusive
Remarks – Method	GLP Certificate. No protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1	0.3	1	2	< 7 days	0
Oedema	0	0	0	1	< 24 hours	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal

Remarks – Results	Very slight to well-defined erythema was noted on all treated sites within one hour after patch removal. Very slight erythema persisted for 72 hours within two animals. Very slight oedema was noted on all two treated animals within one hour after patch removal. All effects on treated skin were fully reversible within 7 days.

CONCLUSION The analogue polymer is slightly irritating to the skin.

TEST FACILITY Safepharm (1997b)

B.3. Eye Irritation – Rabbit

TEST SUBSTANCE Analogue polymer

METHOD OECD TG 405 Acute Eye Irritation/Corrosion (1987)
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation)
Species/Strain Rabbit/New Zealand White
Number of Animals 3 M
Observation Period 72 horus
Remarks – Method GLP Certificate
No significant protocol deviations

RESULTS

Lesion	*Mean Score** *Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva – Redness	0.7	0	0	2	< 72 hours	0
Conjunctiva – Chemosis	0.7	0	0	1	< 72 hours	0
Conjunctiva – Discharge	0.7	0	0	2	< 72 hours	0
Corneal Opacity	0	0	0	0	-	0
Iridial Inflammation	0	0	0	0	-	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal

Remarks – Results

CONCLUSION The analogue polymer is slightly irritating to the eye.

TEST FACILITY Safepharm (1997c)

B.4. Skin sensitisation - Buehler Test

TEST SUBSTANCE Analogue polymer

METHOD OECD TG 406 Skin Sensitisation – Buehler Test (1992)
EC Directive 92/69/EEC B.6 Skin Sensitisation – Buehler Test
Species/Strain Guinea pig/Dunkin-Hartley Albino
PRELIMINARY STUDY Maximum non-irritating concentration: 75%
Topical: 10%, 25%, 50%, 75%
MAIN STUDY
Number of Animals Test Group: 20 M Control Group: 10 M
Vehicle 80% aqueous ethanol (induction), acetone (challenge)
Positive Control Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using 2,4-dinitrochlorobenzene (DNCB).
INDUCTION PHASE Induction concentration:
Topical: 75%
Signs of Irritation None observed
CHALLENGE PHASE
1st Challenge Topical: 75% and 50%
2nd Challenge None
Remarks – Method GLP Certificate
No significant protocol deviations

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		Challenge (75%)		*Challenge (50%)*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	75%, 50%	0/19	0/19	0/19	0/19
Vehicle Control Group	75%, 50%	0/9	0/9	0/9	0/9

Remarks – Results

One animal in the control group had died and one animal in the test group had been killed during the study. Their absence was not considered to have any effect on the integrity of this study.

No signs of systemic toxicity was observed in all other animals. There were no skin reactions observed at the challenge sites for all animals for the duration of the study.

CONCLUSION

There was no evidence of reactions indicative of skin sensitisation to the analogue polymer under the conditions of the test.

TEST FACILITY

Safepharm (1997d)

B.5. Genotoxicity – Bacteria

TEST SUBSTANCE

Analogue polymer

METHOD

OECD TG 471 Bacterial Reverse Mutation Test (1983)
EC Directive 92/69/EEC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria
Plate incorporation procedure (test 1)/Pre incubation procedure (test 2)

Species/Strain

Salmonella typhimurium: TA1535, TA1537, TA98, TA100
Escherichia coli: WP2P, WP2P *uvrA*

Metabolic Activation System

Rat liver homogenate induced with phenobarbital/β-naphthoflavone (10% liver S9 in standard co-factors)

Concentration Range in Main Test

Test 1 with and without metabolic activation: 100, 200, 500, 1,000, 2,500, 5,000 µg/plate
Test 2 with and without metabolic activation: 100, 200, 500, 1,000, 2,500, 5,000 µg/plate

Vehicle

Dimethyl sulfoxide (DMSO)

Remarks – Method

No significant protocol deviations.
Vehicle control and the following positive controls were run concurrently with the test substance:
With metabolic activation: 2-aminoanthracene (all strains)
Without metabolic activation: daunomycin HCl (TA98), acridine mutagen ICR191 (TA1537), *N*-ethyl-*N*'-nitro-*N*-nitrosoguanidine (WP2P *uvrA*), mitomycin C (WP2P) and sodium azide (TA1535 and TA100)

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	-	> 5,000	≥ 5,000	Negative
Test 2	-	> 5,000	> 5,000	Negative
Present				
Test 1	-	> 5,000	≥ 5,000	Negative
Test 2	-	> 5,000	> 5,000	Negative

Remarks – Results

No significant increases in the frequency of revertant colonies were observed for any of the bacterial strains, at any test concentration, either with or without metabolic activation.

	The positive and vehicle controls gave satisfactory responses confirming the validity of the test system.
CONCLUSION	The analogue polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	CTL (1997)

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