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October 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in ClearShield UV 390B

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 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.

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
STD/1485	Milliken Design Inc.	Polymer in ClearShield UV 390B	Yes	≤ 100 tonnes per annum	UV absorber in polyethylene terephthalate (PET) containers

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).

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

Hazard classification	*Hazard statement*
Acute Category 2	H401, Toxic to aquatic life
Chronic Category 2	H411, Toxic to aquatic life with long lasting effects

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 assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and SafetyMilliken

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation processes:
  - 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 during handling of the notified polymer during reformulation processes:
  - Avoid skin contact

- 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 during reformulation processes:

- Gloves
- Safety glasses
- 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(2) of the Act; if
- the function or use of the polymer has changed from UV absorber in polyethylene terephthalate (PET) containers 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.

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet
The (M)SDS of 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

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemical were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Milliken Design Inc. (ABN: 581 420 967 59)
7/860 Doncaster Road
DONCASTER EAST VIC 3109

NOTIFICATION CATEGORY
Standard (Reduced fee notification): Synthetic polymer with Mn < 1000 Da (more than 1 tonne per year)- Comparable agency modular assessment.

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 constituents, residual monomers, impurities, additives/adjuvants, use details, import volume, site of reformulation and identity of manufacturer/recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Particle size, flammability, autoignition temperature, explosive properties, oxidising properties, acute dermal toxicity, acute inhalation toxicity, and genotoxic damage in vivo.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2003), Canada (2010), Korea (2006), New Zealand (2010) and China (2009)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
ClearShield UV 390B (Product containing the notified polymer at > 80% concentration)

OTHER NAME(S)
Uncut ClearShield UV 390B (name on (M)SDS - neat notified polymer)

MOLECULAR WEIGHT
< 1000 Da

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

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Freezing Point	2.0 °C (gel point)	Measured

Boiling Point	Decomposes before boiling from 364.3°C at 101.3 kPa	Measured
Density	1.144 kg/m^3 at 25 °C	Measured
Vapour Pressure	< 2.19x10^{-5} kPa at 25 °C	Estimated using Modified Watson Correlation method
Water Solubility	> 2 g/L at 22 °C	Measured
Hydrolysis as a Function of pH	$t_{1/2}$ = 12.6 at 50 °C, pH = 4.0; $t_{1/2}$ = 42.0 at 25 °C, pH = 7.0; $t_{1/2}$ = 12.8 at 25 °C, pH = 9.0.	Measured
Partition Coefficient (n-octanol/water)	log Pow = 2.03 at 20 - 25 °C	Measured
Adsorption/Desorption	Log K_{oc} = 2.04 – 2.08	Estimated using method developed by Güsten and Sabljic (Güsten, 1995)
Dissociation Constant	Not determined	Not expected to be ionised at environmental pH range of 4-9
Flash Point	> 110 °C at unknown kPa (closed cup)	Measured
Flammability	Not determined	Not expected to be highly flammable based on flash point
Autoignition Temperature	Not determined	Not expected to autoignite based on flash point
Explosive Properties	Not determined	Does not contain any functional groups that imply explosive properties
Oxidising Properties	Not determined	Does not contain any functional groups that imply oxidising properties

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. The notified polymer is susceptible to hydrolysis in water, however, once incorporated into the polymer matrix it is no longer expected to be susceptible to hydrolysis.

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 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 not be manufactured in Australia. The notified polymer will be imported as a component of the product ClearShield UV 390B at > 80% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-50	10-50	50-100	50-100	50-100

PORT OF ENTRY
Sydney and Melbourne

IDENTITY OF RECIPIENTS
The product containing the notified polymer will be supplied to companies involved in the manufacture of PET containers.

TRANSPORTATION AND PACKAGING

ClearShield UV 390B, containing the notified polymer at > 80% concentration will be imported in either polyethylene lined 208.2 L plastic drums or in 1,041 L Shutz totes. The drums will be shipped to Australia by sea or air and the totes will be shipped by sea. Within Australia the products will be transported by road or rail.

USE
ClearShield UV 390B, containing the notified polymer (at > 80% concentration) will be imported as a liquid concentrate for use as a UV absorber in PET containers. The final products (containers) will contain < 0.5% of the notified polymer and will be used to manufacture plastic articles, food and beverage containers, and containers for products for health beauty aid and household products.

OPERATION DESCRIPTION
The notified polymer will be imported as part of a liquid concentrate at > 80% concentration for reformulation into PET pellets and finally plastic containers. The plastic pellets produced during reformulation will contain < 0.5% of the notified polymer and will be used to manufacture plastic articles, food and beverage containers, and containers for products for health beauty aid and household products.

REFORMULATION
The product containing the notified polymer (at > 80% concentration) will be transported to plastics compounding facilities where it will be incorporated into PET pellets containing < 0.5% notified polymer. The compounding process will occur using largely automated processes and closed systems, although some manual transfer steps may be involved. Once in dried pellet form, the notified polymer is trapped in the inert matrix and no longer bioavailable.

The pellets may then be used at various sites to manufacture plastic articles such as food and beverage containers, and containers for products for health beauty, and household products. Final product containers will contain the notified polymer at < 0.5% concentration.

END USE
The finished PET containers containing the notified polymer at < 0.5% concentration will be transported from the manufacturers sites to customers for sale to the general public.

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)*
Process operators at PET manufacturing sites	0.5	250

EXPOSURE DETAILS
Transport and storage
Transport and storage workers may only come into contact with the notified polymer at > 80% concentration in the event of accidental rupture of containers.

Reformulation of products
Dermal and ocular exposure of workers to the notified polymer (at > 80% concentration) may occur at compounding sites during formulation of PET pellets, particularly when charging the mixing tanks and while performing maintenance and cleaning of equipment and drum reconditioning. Inhalation exposure is not expected due to the low vapour pressure of the notified polymer. Dermal and ocular exposure is expected to be minimised through the use of enclosed systems and through the use of personal protective equipment (PPE) such as coveralls, safety glasses and impervious gloves.

Workers at plastic processing plants may be exposed to plastic pellets containing the notified polymer at < 0.5% concentration. While dermal exposure to the pellets may occur, the notified polymer will be reacted into the PET matrix and will not be available for exposure. Exposure to the pellets is expected to be minimised through the use of enclosed systems and through the use of personal protective equipment (PPE).

End use
Retail workers may come into contact with plastic articles containing the notified polymer at < 0.5% but as it is trapped in the polymer matrix, it will be unavailable for exposure.

6.1.2. Public Exposure
The public will be exposed to various plastic articles containing the notified polymer at < 0.5% concentration, such as food and beverage containers, and containers for health, beauty aid and household products.

Migration into foods
The notified polymer has undergone migration testing studies using various food simulants under different storage conditions. The notified polymer showed 0.0054 mg/ 6 dm^2 migration level in 95% ethanol with no leaching of the test material in 10% ethanol at concentrations up to 0.02 mg/ 12.9 dm^2. These experiments demonstrate that the notified polymer is expected to be bound into the PET matrix and not migrate in the food it comes in contact with, therefore being unavailable for exposure. This is in agreement with the notifier's specification that the polymer is designed to be non-extractable and non-migrating.

Based on the information provided, secondary public exposure to the notified polymer from migration into food and beverages in contact with the PET containers (containing < 0.5% notified polymer) is not expected.

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	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Rat, repeat dose (oral gavage) toxicity – 28 days	NOAEL = 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* Chromosome Aberration	non genotoxic
Genotoxicity – *in vitro* Mammalian Cell Gene Mutation Test	non genotoxic

Toxicokinetics, metabolism and distribution.
The notified polymer has a relatively low molecular weight (< 1000 Da); hence, there is some potential for absorption across biological membranes. However, given that the notified polymer has high water solubility and relatively low partition coefficient, dermal absorption is expected to be limited.

Acute toxicity.
The notified polymer was found to be of low toxicity in a rat acute oral toxicity study with an LD50 > 2000 mg/kg bw.

Acute dermal and inhalation toxicity data were not provided for the notified polymer. The notified polymer has a relatively low molecular weight (< 1000 Da); hence, there is some potential for absorption across biological membranes. However, given the notified polymer is of low toxicity via the oral route, has high water solubility and relatively low partition coefficient, significant toxic effects via dermal absorption are not expected. The vapour pressure of the notified polymer is low ($\leq 2.19 \times 10^{-5}$ kPa at 25 °C) and therefore inhalation of the vapour of the notified polymer is not expected to occur under normal environmental conditions.

Irritation and sensitisation.
The notified polymer was found to be non-irritating to the skin and eye in studies conducted in rabbits. It is noted however, that yellow coloured staining was observed around the treated eyes of all animals throughout the study. Moderate conjunctival irritation was observed in all treated eyes one hour after instillation of the test substance and minimal conjunctival irritation noted at the 24 and 48 hour post treatment observations. At 72 hours post treatment, all eyes appeared normal. Therefore, based on the information provided, the notified polymer is expected to be non-irritating to the skin and may be mildly irritating to the eyes.

A mouse local lymph node assay (LLNA) performed using the notified polymer found no evidence of sensitization.

Repeated Dose Toxicity.
A 28 day repeated dose oral toxicity study was conducted using the notified polymer in the rat. No clinical signs of toxicity were noted in any test animals. Males treated at 1000 mg/kg bw/day showed an increase in absolute and relative liver weights compared to the control group. Centrilobular hepatocyte hypertrophy was observed in the livers of male and female animals dosed with 1000 mg/kg bw/day. These effects were not considered to represent adverse effects and a NOAEL of 1000 mg/kg bw/day was determined by the study authors.

Mutagenicity/Genotoxicity.
The notified polymer was non-mutagenic in a bacterial reverse mutation test. It was also negative in a human lymphoma chromosome aberration assay and a mouse cell gene mutation test.

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
The notified polymer was found to be of low toxicity via the oral route; it is not irritating to the skin but may be mildly irritating to the eyes. There is the potential for dermal and ocular exposure to the notified polymer at > 80% concentration during reformulation. However, exposure is expected to be limited by the use of appropriate PPE including coveralls, impervious gloves and safety glasses. End use workers may also come into contact with plastic articles containing the notified polymer at < 0.5%. However, the polymer will be trapped in the PET matrix and be unavailable for exposure. Therefore, based on the exposure pattern, the expected use of PPE and low hazardous nature of the notified polymer, the risk to workers is not considered to be unreasonable.

6.3.2. Public Health
The public will be frequently exposed to plastic articles such as food and beverage containers containing the notified polymer at < 0.5% concentration. However, the notified polymer will be trapped in the PET matrix and will, therefore, not be bioavailable. Furthermore, migration studies indicate that the polymer is not expected to migrate from the plastic containers to food or beverages in contact with them in any notable concentrations. Thus, considering the stability, low end use concentration and low hazardous nature of the notified polymer, the risk to the general public 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 product containing the notified polymer will be imported into Australia and shipped to industrial facilities in the original containers. Significant release of the notified polymer to the environment is not expected to occur from storage and transportation.

RELEASE OF CHEMICAL FROM USE
The product containing the notified polymer will be used in the manufacturing of polyethylene terephthalate (PET) pellets. The plastic compounding process is expected to be largely automated and occur in closed systems. Once in dried pellet form, the notified polymer will be trapped in the inert matrix. Therefore, no significant release of the notified polymer is expected from its use. The generated waste, if any, during plastic manufacture is expected to be collected for safe disposal by a waste management company.

RELEASE OF CHEMICAL FROM DISPOSAL
The majority of the notified polymer will share the fate of end-use plastic articles and be disposed of to landfill or subjected for recycling of PET products. Empty containers are expected to be rinsed by water and the rinsate will be reused.

7.1.2. Environmental Fate

The majority of the notified polymer will be incorporated into end-use plastic articles. It is expected to be physically bound into an inert matrix and, in this form, is not expected to be mobile or bioavailable. Used plastic articles are expected to be disposed of to landfill or subjected for recycling of PET products at the end of their useful life. In landfill or, by thermal decomposition, the notified polymer will eventually degrade to form water, oxides of carbon and nitrogen.

The notified polymer attained 29% biodegradability over 28 days (OECD TG 301D), indicating the notified polymer is not readily biodegradable. The notified polymer is not expected to bioaccumulate in aquatic organisms based on the measured low partition coefficient (n-octanol/water). Furthermore, the notified polymer is not considered to be released into or partition to the aquatic compartment in significant quantities based on its reported use pattern.

7.1.3. Predicted Environmental Concentration (PEC)

The PEC has not been calculated as very limited aquatic exposure is expected based on the reported use pattern.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below.

Endpoint	*Result*	*Method*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) = 8.53 mg/L	US. EPA OPPTS 850.1075 (3)	Toxic to fish
Daphnia Toxicity	EC50 (48 h) > 141mg/L	US.EPA OPPTS 850.1010 (2)	Not harmful to aquatic invertebrates
Algal Toxicity	EC50 (96 h) > 100 mg/L	US.EPA OPPTS 850.5400	Not harmful to algae

Under the Globally Harmonised System of Classification (GHS) and Labelling of Chemicals (United Nations, 2009), the notified polymer is classified as toxic to fish and not harmful to aquatic invertebrates or algae. Based on the toxicity of the notified polymer to fish, the notified polymer is formally classified under the GHS as "Acute category 2; Toxic to aquatic life". Based on the acute toxicity and biodegradability data, the notified polymer is classified as "Chronic category 2; Toxic to aquatic life with long lasting effects".

7.2.1. Predicted No-Effect Concentration

The ecotoxicity endpoint for fish (LC50 = 8.53 mg/L) was used to calculate the Predicted No-Effect Concentration (PNEC). An assessment factor of 100 was appropriately used as acute toxicity endpoints for the notified polymer are available from three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (fish, 96 h)	8.53	mg/L
Assessment Factor	100	
PNEC:	85.3	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient, Q (= PEC/PNEC), has not been calculated since a PEC is not available. The notified polymer is toxic with long lasting effects to aquatic organisms. However, the notified polymer is not expected to bioaccumulate in organisms and significant release of the notified polymer to the aquatic environment is not expected based on the proposed use pattern. Therefore, based on the assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Freezing Point -2.0 °C

Method Non OECD method. 10-30 grams of the test material in a test tube was submerged into an ice bath. A thermometer was inserted into the test tube and used to stir. The freezing point is noted when the liquid mass becomes predominantly a thick, opaque mass.
Remarks The results of this test were not described.
Test Facility Milliken (1999)

Boiling Point Decomposition from 364.3 °C under nitrogen atmosphere

Method In house thermogravimetric analysis
Remarks The start temperature was room temperature (not specified), with a scan rate of 20 °C/min and an end temperature of 500 °C under nitrogen atmosphere.
Test Facility Milliken (2013)

Density (Specific gravity) 1.144 kg/m^3 at 25 °C

Method In house determination of Specific gravity relative to water.
Remarks No unusual behaviour of the compound was observed during the determination,
Test Facility Milliken (Undated a)

Water Solubility > 2 g/L at 22 °C

Method In-house method. The test substance was dissolved in ethanol at 100, 200, 1000 and 2000 mg/L. No undissolved product or turbidity was observed in any of the solutions. The absorbance of each solution was measured by spectrophotometer.
Remarks Flask Method. The measured absorbance increased linearly with the increase of concentrations, indicating that the test substance is completely soluble in water at each prepared concentration. Therefore, the water solubility of the test substance was considered to be > the highest concentration.
Test Facility Milliken Chemical (Undated b)

Hydrolysis as a Function of pH $t_{1/2}$ = 12.6 at 50 °C, pH = 4.0;
$t_{1/2}$ = 42.0 at 25 °C, pH = 7.0;
$t_{1/2}$ = 12.8 at 25 °C, pH = 9.0.

Method OPPTS 835.2110

pH	*T (°C)*	*$t_{½}$ (days)*
4	50	12.58
7	25	42.0
	50	4.14
9	25	12.8
	50	2.58

Remarks The degradation of the test substance was determined to be > 10% at 50 °C at the test pH range. As the pH and temperature increases, the extent of degradation increases. The test substance is considered to be hydrolytically unstable.
Test Facility Milliken Chemical (2003a)

Partition Coefficient (n-octanol/water) log Pow = 2.03 at 20 – 25 °C

Method In-house method. The test substance was dispersed into a mixture of octanol and DI water. After 30 minutes stirring, the mixture was allowed to separate for 1 hour. Samples were taken from each layer and diluted in methanol. The absorbance of the sample from each layer was measured using a UV/Vis spectrophotometer.

Remarks Flask Method. Based on the absorbance of each phase, the concentration of the test substance in water and octanol phases was estimated and the partition coefficient was derived.
Test Facility Milliken Chemical (Undated c)

Flash Point > 110 °C at unknown kPa

Method In house closed cup flash point apparatus.
Remarks The test substance was a viscous liquid and remained unchanged over the temperature range at which it was tested.
Test Facility Milliken (Undated d)

Viscosity 2650 cps at 21.5°C

Method In house method using a viscometer.
Test Facility Milliken (2010)

Stability Stable in:
95% ethanol for 4.5 hours at 60°C and 10 days at 40°C
3% acetic acid for 2 hours at 121°C and 10 days at 40°C
Isooctane for 2 hours at 60°C and 2 days at ambient temperature.

Method In house method. The purpose of this study was to test the stability of the notified polymer in 10% ethanol, 3% acetic acid, 95% ethanol and isooctane. A 1.25 ug/mL solution of test substance was prepared in methanol. Samples containing various amounts of this solution in stainless steel were then subjected to a number of different conditions to test the stability of the substance. The results were analysed by scanning using a spectrophotometer.

Results

Solvent	Concentration of test substance (ppb)	Recovery level (ppb)
3% Acetic acid*	10	10.3
3% Acetic acid*	50	49.7
10% Ethanol**	50	0
95% Ethanol*	10	10.6
95% Ethanol*	50	51.7
Isooctane*	10	10.7
Isooctane*	50	47.2

*each test was performed in triplicate, average results shown.
**each test was performed in duplicate, average results shown
Recoveries in the range of 92-111% were obtained in 3% acetic acid, 95% ethanol and isoctane. Some hydrolysis break down of the test substance appears to occur in 10% ethanol.

Test Facility Milliken (2003b)

Migration study 1 Notified polymer 0.0054 mg/ 6 dm^2 Migration level in 95% ethanol

Method In house method. Uncoloured control PET samples containing the notified polymer were blow moulded into 2 litre PET soda bottles. Plaques were cut into the side of the bottles. Extraction studies were performed under French Positive Extraction conditions in 10% ethanol, 3% acetic acid, 95% ethanol or isooctane. Extracts were analysed using a spectrophotometer with a 10 cm path length cell with a detection limit of 0.01mg. Calibration curves were prepared in a separate experiment using known amounts of test material. The samples were placed in ovens and subjected to the conditions described below.

Extraction solvents/conditions:
Solvent A - 10% Ethanol

Solvent B - 3% Acetic acid
Solvent A&B conditions: 121°C for 2 hours followed by 40°C for 10 days
Solvent C - 95% Ethanol
Solvent C conditions- 60°C for 4.5 hours followed by 40°C for 10 days
Solvent D - Isooctane
Solvent D conditions- 60°C for 2 hours followed by room temp (22-23°C) for 2 days
Plaque thickness: 0.017 inches
Plaque Area: 0.85 dm^2

Results

Stimulant	Absorbance UV 390B in Migrate (au)	Concentration in Test medium (mg/ 12.9 dm^2)	Migration Level (mg/ 6 dm^2)
10% Ethanol	< 0.0035 < 0.0035 Average < 0.0035 (Not detected)	< 0.0100	< 0.0047
3% Acetic acid	< 0.0035 < 0.0035 Average < 0.0035 (Not detected)	< 0.0100	< 0.0047
95% Ethanol	0.0042 0.0046	0.0117	0.0054
100% Isooctane	(not detected)	< 0.0100	< 0.0047

Clearshield UV was only detected in the 95% ethanol test.

Test Facility Milliken (2003c)

Migration study 2 Notified polymer

Method In house method. Uncoloured control PET samples containing the notified polymer were blow moulded into 2 litre PET soda bottles. Plaques were cut into the side of the bottles. Extraction studies were performed under French Positive Extraction conditions in 10% ethanol. Extracts were analysed using HPLC analysis.

Extraction solvents/conditions:
Solvent A - 10% Ethanol
Solvent condition- 121°C for 2 hours followed by 40°C for 10 days
Plaque thickness: 0.017 inches
Plaque Area: 0.85 dm^2

Results Neither the notified polymer nor its break down product could be detected during this study.

Conclusion No leaching of the test material was noted at concentrations up to 0.02mg/ 12.9 dm^2.

Test Facility Milliken (2003d)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure.
Species/Strain	Rat/Sprague-Dawley CD
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 F	2000	0/5

LD50	> 2000 mg/kg bw
Signs of Toxicity	There were no signs of toxicity observed in this study.
Effects in Organs	There were no effects observed in organs.
Remarks - Results	The oral LD50 value of the test substance was estimated to be > 2000 mg/kg bw.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	SafePharm (2003a)

B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion EC Council Regulation No 440/2008 B.4 Acute Toxicity (Skin Irritation)
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations After a single 4 hr application with semi-occlusive dressing, animals were observed and scored according to the Draize system for any irritation for a period of 72hrs.

RESULTS

Remarks - Results	No evidence of skin irritation was noted in any animal at any time point during the study.
CONCLUSION	The notified polymer is non-irritating to the skin.
TEST FACILITY	Harlan (2012a)

B.3. Irritation – eye

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Council Regulation No 440/2008 B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3

Observation Period	72 hours
Remarks - Method	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	0.7	0.7	2	< 72 h	0
Conjunctiva: chemosis	0.7	0.7	0.7	2	< 72 h	0
Conjunctiva: discharge	0.3	0	0.3	2	< 48 h	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	Yellow coloured staining was observed around the treated eyes of all animals throughout the study. Moderate conjunctival irritation was observed in all treated eyes one hour after instillation of the test substance and minimal conjunctival irritation noted at the 24 and 48 hour observations. At 72 hours all eyes appeared normal.
CONCLUSION	The notified polymer is non-irritating to the eye.
TEST FACILITY	Harlan (2012b)

B.4. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)
Species/Strain	Mouse/CBA/Ca
Vehicle	Acetone/olive oil (4:1)
Remarks - Method	No significant protocol deviations. Following a preliminary screening test in which no clinical signs of toxicity were noted at a concentration of 100%, this concentration was selected for the main test.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	1552.49	-
25	1423.58	0.92
50	1284.25	0.83
100	1803.43	1.16
Positive Control		
25	Not detailed	5.76

Remarks - Results	There were no unscheduled deaths during the study. There were no signs of systemic toxicity noted in either the test or control animals.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer.
TEST FACILITY	Harlan (2012c)

B.5. Repeat dose toxicity

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/ Wistar Han: RccHan: WIST
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: None
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5 M/5 F	0	0/10
low dose	5 M/5 F	30	0/10
mid dose	5 M/5 F	300	0/10
high dose	5 M/5 F	1000	0/10

Mortality and Time to Death
There were no unscheduled deaths throughout the study.

Clinical Observations
There were no clinical signs of toxicity observed.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
There were no toxicologically significant changes observed in clinical chemistry, haematology or urinalysis.

Effects in Organs
At necropsy, males treated at 1000 mg/kg bw/day showed an increase in absolute and relative liver weights compared to the control group.
Microscopically, centrilobular hepatocyte hypertrophy was observed in the livers of male and female animals dosed with 1000 mg/kg bw/day. While a number of other microscopic sporadic abnormalities were noted, there were no significantly increased incidences in treated verses control animals and thus not considered toxicologically relevant.

Remarks – Results
While some treatment related changes were observed in the livers of high dose animals, however the study authors considered these to be adaptive and thus not adverse in nature.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day in this study, based on absence of adverse effects at this dose.

TEST FACILITY	Harlan (2012d)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	Liver preparations (S9 mix) from rats treated with phenobarbital and ß-

	naphthoflavone
Concentration Range in Main Test	a) With metabolic activation: 50-5000 µg/plate b) Without metabolic activation: 50-5000 µg/plate
Vehicle	Distilled water
Remarks - Method	In order to select appropriate dose levels for use in the main study, a preliminary test was carried out to determine the toxicity of the test material. Aliquots of either test substance, positive, or negative control solution were tested in triplicate at five concentrations (50-5000µg/plate). The negative control was distilled water and positive controls were sodium N-ethyl-N'-nitro-N-nitrosoguanidine, 9-aminoacridine, mitomycin C and 4-nitroquinoline-1-oxide in the absence of S9 mix and 2-aminoanthracene, benzo[a]pyrene and 1,8-dihydroxyanthraquinone in the presence of S9 mix.

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	≥ 5000	No precipitation	Negative
Test 2		≥ 5000	No precipitation	Negative
Present				
Test 1		> 5000	No precipitation	Negative
Test 2		> 5000	No precipitation	Negative

Remarks - Results	No precipitation was observed at any dose level either with or without metabolic activation. The test substance caused cytotoxicity in TA100 (experiments 1 and 2), and TA1535 and TA1537 (experiment 1 only) at the highest concentration in the absence of S9 mix. No toxicity was noted in any other strains with or without S9 mix. No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, at any dose of the test substance, either with or without metabolic activation. All the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm (2003b)

B.7. Genotoxicity – in vitro

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.
Cell Type/Cell Line	Human lymphocytes
Metabolic Activation System	Liver preparations (S9 mix) from rats treated with phenobarbital and ß-naphthoflavone
Vehicle	DMSO

Remarks - Method The positive controls used in the study were Mitocycin C (without metabolic activation) and Cyclophosphamide (with metabolic activation).

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 156.25*, 312.5*, 625*, 1250, 1875, 2500	4	24
Test 2	0*, 78.13*, 156.25*, 312.5*, 625, 781.25, 937.5	24	-
Present			
Test 1	0*, 312.5*, 625*, 1250*, 1875, 2500, 3750	4	24
Test 2	0*, 156.25*, 312.5*, 625*, 1250*, 2500, 3750	4	24

*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	≥ 2500	≥ 1250	> 2500	Negative
Test 2	≥ 1250	≥ 625	> 937.5	Negative
Present				
Test 1	≥ 5000	≥ 1250	> 3750	Negative
Test 2		≥ 1250	> 3750	Negative

Remarks - Results High toxicity was observed in experiment 1 at concentrations at and above 1250 µg/mL with and without metabolic activation. The maximum dose selected for metaphase analysis was limited due to the toxicity of the test substance. In the second experiment high levels of toxicity were observed at and above 625 µg/mL in the absence of metabolic activation and at and above 1250 µg/mL in the presence of metabolic activation.

No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation.

All the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

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

TEST FACILITY SafePharm (2003c)

B.8. Genotoxicity – in vitro

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 Lymphoma L5178Y cells
Metabolic Activation System Liver preparations (S9 mix) from rats treated with phenobarbital and ß-naphthoflavone
Vehicle DMSO
Remarks - Method Selection of doses was done on the basis of a pre-experiment

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period(h)*	*Expression Time(h)*
Absent			
Test 1	0*, 15.63*, 31.25*, 62.5*, 93.75*, 125*, 150*	3	48
Test 1b	0*, 31.25*, 62.5*, 125*, 250*, 375, 500	24	48
Test 1c	0*, 12.5*, 25*, 50*, 75*, 100*, 150*, 200*, 300, 400, 500	3	48
Test 2	0*, 100*, 107*, 150*, 175*, 200*, 214	3	48
Test 2b	0*, 50*, 100*, 150*, 200*, 250*, 300*	24	48
Present			
Test 1	0*, 62.5*, 125*, 187.5*, 250*, 375*, 500*	3	48
Test 2	0*, 100*, 150*, 200*, 214*, 300*, 350*	3	48

*Cultures selected for metaphase analysis. Positive controls used in the study were ethylmethanesulphonate (without metabolic activation) and Cyclophosphamide (with metabolic activation).

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	≥ 500			
Test 1		> 150	> 150	Negative
Test 1b		≥ 250	> 500	Negative
Test 1c		≥ 200	> 200	Negative
Test 2		≥ 200	> 214	Negative
Test 2b		≥ 300	> 300	Negative
Present				
Test 1		≥ 500	> 500	Negative
Test 2		≥ 300	> 350	Negative

Remarks - Results

The test substance did not induce any statistically significant increases in the mutant frequency at any tested concentration in each exposure group 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 mutagenic to the mouse lymphoma thymidine kinase locus using the cell line L5178Y treated in vitro under the conditions of the test.

TEST FACILITY

SafePharm (2003d)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Activated sewage effluent
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved oxygen measurement
Remarks - Method	The test was conducted in accordance with the test guideline above without significant deviation from the protocol. Good Laboratory Practice was followed.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	15	7	68
14	17	14	76
21	13	21	79
28	29	28	77

Remarks - Results	Biodegradation of the reference substance was determined to be 63% after five days of incubation and 79% by the end of the test. With the presence of the test substance in the toxicity control, biodegradation of the reference substance was 51% after five days, indicating that the inoculums was viable and the test substance did not inhibit the activity of the inoculum. All validity criteria for the test were satisfied.
CONCLUSION	The notified polymer is not readily biodegradable
TEST FACILITY	Huntingdon (2003)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	US.EPA Ecological Effects Testing Guidelines OPPTS 850.1075 (3) Acute Toxicity for Fish - Flow-through.
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	130-160 mg $CaCO_3$/L
Analytical Monitoring	Spectrophotometer
Remarks – Method	Five fish were exposed to the test media under static condition in the range-finding test. After 96 hours exposure, 100% mortality was observed at the test concentration of 100 mg/L. Based on the result obtained in the range-finding test, the flow-through definitive test was performed in accordance with the guideline above. No significant deviation from the protocol was reported.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality (%)*

Nominal	*Actual*		*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	-	20	0	0	0	0	0
6.5	5.65	20	0	0	0	0	0
13	10.4	20	0	0	20	70	85
25	21.8	20	85	100	100	100	100
50	45.8	20	100	100	100	100	100
100	93	20	100	100	100	100	100

LC50	8.53 mg/L at 96 hours (95% confidence limits:7.66 - 9.49 mg/L)
NOEC	5.65 mg/L at 96 hours.
Remarks – Results	Loss of equilibrium, irregular respiration, and/or fish lying on the bottom of the test chamber were observed in the 10.4 and 21.8 mg/L test preparations during the exposure. At the test concentration of 21.8 mg/L, all surviving fish exhibited loss of equilibrium and irregular respiration, and lay on the bottom of the test chamber when exposed to the test preparation for 6 hours.

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CONCLUSION	The notified polymer is toxic to fish
TEST FACILITY	ABC (2003a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	US.EPA Ecological Effects Testing Guidelines OPPTS 850.1010 (2) Acute Toxicity for Daphnia – Flow-Through
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	130-160 mg $CaCO_3$/L
Analytical Monitoring	Spectrophotometer
Remarks - Method	Ten daphnids were exposed to the test media under static condition in the range-finding test. After 48 hours exposure, 0% immobility was observed at the test concentration of 100 mg/L. Based on the result obtained in the range-finding test, the flow-through definitive test was performed in accordance with the guideline above. No significant deviation from the protocol was reported.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	-	20	0	0
13	7.33	20	0	0
25	17	20	0	0
50	34.1	20	0	0
100	64.8	20	0	0
200	141	20	0	0

EC50	>141 mg/L at 48 hours
NOEC	141 mg/L at 48 hours
Remarks - Results	One daphid was quiescent at the measured concentration of 141 mg/L during the exposure time of 48 hours. Although mean measured concentrations ranged from 56-71% of the nominal concentrations, no residues of the test substance were detected in

the control or the test preparations. Furthermore, recovery of test substance in the fresh diluter stock solution was 90% of the nominal concentration and recovery in the old diluter stock solutions ranged from 91-106% of the nominal concentration. Therefore, the concentration change of the test substance in the test media was considered to be due to the instability of the test substance.

CONCLUSION The notified polymer is not harmful to aquatic invertebrates

TEST FACILITY ABC (2003b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified polymer

METHOD US.EPA Ecological Effects Testing Guidelines (3) OPPTS 850.5400 Algal Inhibition Test – Static.

Species	*Selenastrum Capricornutum*
Exposure Period	96 hours
Concentration Range	Nominal: Control, 0.10, 1.0, 10, 100 and 1000 mg/L Actual: Not determined
Auxiliary Solvent	None
Water Hardness	N/A
Analytical Monitoring	Hemacytometer and optical microscope
Remarks - Method	A range-finding test was conducted for 96 hours under continuous fluorescent lighting. The results in the range-finding test indicated that 96-hour EC50 was greater than 100 mg/L. Therefore, a definitive test was not performed and the results were reported based on the range-finding test.

RESULTS

Biomass		*Growth*	
E_bC50	*NOEC*	*E_rC50*	*NOE_rC*
mg/L at 96 h	*mg/L*	*mg/L at 96 h*	*mg/L*
-	-	> 100 mg/L	10 mg/L

Remarks - Results No visible precipitate or surface film was observed in the test solutions throughout the test. The actual concentration for the test substance in the test preparations was not determined during the test and the results reported above are based on nominal concentrations.

Percentage change in cell growth after 96 hours exposure ranged from +59% at 10 mg/L to -99% at 1000 mg/L. Analysis of variance indicated significant inhibition of cell growth, as compared to the control, at the nominal concentrations of 100 and 1000 mg/L at 96 hours.

CONCLUSION The notified polymer is not harmful to algae

TEST FACILITY ABC (2003c)

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