File No: STD/1536

November 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Polyplex ABU Resin

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.

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/1536	Nuplex Industries (Aust) Pty Ltd	Polymer in Polyplex ABU Resin	Yes	≤ 1000 tonnes per annum	Component of composite materials

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is 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. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Skin sensitisation (Category 1)	H317: May cause an allergic skin reaction

Based on the available information, the notified /polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R43: May cause sensitisation by skin contact:

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 3)	H402 - Harmful to aquatic life
Chronic (Category 3)	H412 - Harmful to aquatic life with long lasting effects

Human health risk assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational setting, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - Skin sensitisation (Category 1) – H317: May cause an allergic skin reaction

The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present and the intended use/exposure scenario.

Health Surveillance

- As the notified polymer is a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

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:
  - 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]:
  - Avoid contact with skin

- 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:
  - Coveralls
  - Safety goggles
  - Impervious gloves

  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

- 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

Storage

- The handling and storage of the notified polymer should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by 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 component of composite materials or is likely to change significantly;
- the amount of polymer being introduced has increased, or is likely to increase, significantly;
- the method of manufacture of the polymer in Australia has changed, or is likely to change, in a way that may result in an increased risk of an adverse effect of the polymer on occupational health and safety, public health, or the environment;
- 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 product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Nuplex Industries (Aust) Pty Ltd (ABN: 25 000 045 572)
Building I, Suite 15, 22 Powers Rd
Seven Hills NSW 2147

NOTIFICATION CATEGORY
Standard: Synthetic polymer with Mn < 1,000 Da (more than 1 tonne 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, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, manufacture/import volume, site of manufacture/reformulation and identity of manufacturer/recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical, human health and environmental endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polyplex ABU Resin (contains the notified polymer at ~ 60% concentration)

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference GPC and FTIR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
100%

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< 10 °C	Estimated
Boiling Point	Not determined	Undergoes decomposition prior to boiling
Density	1,100 kg/m^3 at 20 °C	Analogue data
Vapour Pressure	Not determined	Expected to be low based on the molecular weight and viscosity
Water Solubility	Not determined	The notified polymer is mainly composed of hydrophobic species and is not expected to be soluble in water
Hydrolysis as a Function of pH	Not determined	The notified polymer contains functional groups that are expected to hydrolyse very slowly in the environmental pH

		range (4-9)
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to partition from water to octanol based on its hydrophobic structure
Adsorption/Desorption	Not determined	The notified polymer is expected to partition to soil/sediment from water based on its hydrophobic structure
Dissociation Constant	Not determined	The notified polymer does not contain dissociable functional groups
Flash Point	31 °C (closed cup)	Measured/(M)SDS The flashpoint has been determined on the resin solution as the polymer will not be available in its primary form. The anticipated flashpoint of the polymer is expected to be > 100^0C
Flammability	Not determined	At elevated temperatures the notified polymer is expected to decompose.
Autoignition Temperature	Not determined	Not expected to auto-ignite under normal conditions of use.
Explosive Properties	Not determined	Not expected to be explosive based on structure.
Oxidising Properties	Not determined	Not expected to be oxidising based on structure.

DISCUSSION OF PROPERTIES

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 for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be manufactured and imported into Australia as a resin solution at ~ 60% concentration. The notified polymer may also be imported into Australia as a component of a reformulated product at < 60% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 700	< 800	< 900	< 1000	< 1000

PORT OF ENTRY
Sydney and Brisbane

TRANSPORTATION AND PACKAGING
When manufactured within Australia, the resin solution containing the notified polymer at ~60% concentration will be packed off into intermediate bulk containers (IBC's) or steel drums. When imported, the resin solution will be packed in 200 L steel drums.

USE
The notified polymer will be used in the manufacture of sanitary ware products such as acrylic baths and shower trays.

OPERATION DESCRIPTION

Manufacture of the notified polymer

When the notified polymer is manufactured within Australia, the reaction will take place within a registered pressure vessel with jacketed and internal cooling systems. The liquid reactants will be pumped in the reaction vessel using dedicated lines and any solid reactants will be transferred either manually or with a hoist. Once the manufacture of the notified polymer is complete, it will be transferred through dedicated lines into thinning tanks. The resulting resin solution containing the notified polymer at ~60% concentration will be pumped through sealed filters and packaged directly into 1 tonne IBC's or steel drums for transport. Quality control personnel will be required to sample the notified polymer.

Reformulation into finished resins

After manufacture or importation, the resin solution containing the notified polymer will be transferred to various manufacturers of composite sanitary ware, where the resin solution will be charged (pumped) to dedicated mixing tanks and blended with other raw materials to produce finished resins. The reformulation process is envisaged to be fully automated and performed under controlled conditions.

Manufacture of sanitary ware products

The finished resins containing the notified polymer will be used to reinforce thermoformed acrylic bath and shower trays as well as casting and resin transfer moulding (RTM) processes to manufacture sanitary ware 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	1	10
Warehouse/store	8	30
Manufacture/blending	2	50
QC/testing	1	50
Filling	1	50
Dispatch	1	150
Industrial end users	8	200

EXPOSURE DETAILS

It is anticipated that transport and warehouse/store personnel would only be exposed to the notified polymer in the event of an accident.

Manufacture of the notified polymer

Dermal and ocular exposure to the notified polymer at up to 100% concentration may occur during connection and disconnection of transfer lines, quality control testing and equipment cleaning/maintenance. Exposure to the notified polymer at other times is expected to be negligible given the manufacturing process, including the packing off process, will be largely enclosed and automated. Exposure to the notified polymer is expected to be minimised by the stated use by the notifier of PPE (including safety glasses, gloves, and coveralls).

Reformulation into finished resins

Dermal and ocular exposure to the notified polymer at up to 60% concentration may occur during connection and disconnection of transfer lines, quality control testing and equipment cleaning/maintenance. Exposure to the notified polymer at other times is expected to be negligible given the reformulation process will be largely enclosed and automated. Exposure to the notified polymer is expected to be minimised by the stated use by the notifier of PPE (including safety glasses, gloves, and coveralls).

Manufacture of sanitary ware products

The finished resins containing the notified polymer will be used to manufacture sanitary ware products in casting and resin transfer moulding (RTM) processes. Dermal and ocular exposure to the notified polymer (≤ 60%

concentration) may occur when using casting systems. Negligible exposure is expected when using the closed RTM process. Exposure is expected to be minimised by the stated use by the notifier of PPE (including safety glasses, gloves, boots and protective clothing).

Where the notified polymer is used in thermoforming applications, the reformulated resin containing the notified polymer (at ≤ 60% concentration) will be sprayed onto An enclosed, automated mechanical cutting and grinding machine is used to trim the article to size. The machinery is typically enclosed and fitted with extraction mechanisms to avoid release of airborne dust.

Once the resins have been cured to form composite sanitary ware articles, the notified polymer will be incorporated into a solid, inert, polymer matrix and will not be available for exposure.

6.1.2. Public Exposure

The notified polymer is intended for industrial use only, and will not be available to the public. Direct exposure would therefore not be expected. Indirect exposure from accidental spills or environmental sources may be possible, but are unlikely for the proposed use.

Members of the public may experience dermal exposure to composite sanitary ware articles containing the notified polymer. However, in such products the notified polymer will be bound within a polymer matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer. The results from toxicological investigations conducted on a close analogue of the notified polymer (analogue 1) are summarised in the table below. Analogue 1 and the notified polymer are considered to be very similar in chemical composition and physico-chemical properties and therefore the endpoints presented below are likely to reflect the toxicity of the notified polymer. Details of the studies of analogue 1 can be found in Appendix A.

Endpoint	*Result and Assessment Conclusion*
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Mouse, skin sensitisation – Local lymph node assay	evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vivo mouse micronucleus test	non genotoxic

Toxicokinetics.

Absorption of the notified polymer across biological membranes is likely to be limited, based on the relatively high molecular weight (> 500 Da) and expected low water solubility. However, there are significant levels of low molecular weight species and the possibility of absorption cannot be ruled out.

Acute toxicity.

Analogue 1 was found to be of low acute dermal toxicity in both an acute dermal toxicity sighting study and limit test. Based on this the notified polymer is expected to be of low toxicity by the dermal route.

No acute oral toxicity study was conducted on analogue 1 as due to its highly viscous nature an accurate dose could not be delivered according to the accepted test methodology. As a worst case scenario, the notifier has provided information on the acute oral toxicity for the monomer (analogue 2) in the notified polymer containing the functional group of concern that is most likely to contribute to human health toxicity in the notified polymer. The LD50 values for analogue 2 have been reported to be ~ 1,000 mg/kg bw. Therefore, based on this information, the notified polymer may be at most harmful by the oral route. However, given the relatively high molecular weight and expected low water solubility, absorption of the notified polymer across the gastrointestinal tract is likely to be limited. Therefore, based on the weight of evidence, the potential for the notified polymer to cause acute oral toxicity is expected to be low; however, it cannot be ruled out.

No acute inhalation toxicity study was provided. Given the low vapour pressure of the notified polymer, inhalation exposure is not expected unless aerosols or mists are formed.

Irritation and sensitisation.
Analogue 1 was found to be non-irritating to the skin. Based on this the notified polymer is not expected to be irritating to the skin.

An eye irritation study was not conducted for analogue 1. The notified polymer does not contain any structural alerts associated with eye irritation and it is not expected to be irritating to the skin; hence, the notified polymer is not expected to be an eye irritant.

Analogue 1 was positive in a local lymph node assay with a concentration of approximately 30.43% corresponding to a Stimulation Index of 3 (also referred to as EC3). Based on this the notified polymer may be a weak sensitiser.

Repeated dose toxicity.
There are no repeated dose toxicity data available for analogue 1. As a worst case scenario, the notifier has provided information on the repeated dose toxicity for the monomer (analogue 2) in the notified polymer containing the functional group of concern that is most likely to contribute to human health toxicity in the notified polymer.

Oral studies in rats indicate that high doses of analogue 2 (> 100 mg/kg bw/day) can lead to kidney damage; however, only minor effects were observed in studies at low doses (< 100 mg/kg bw/day). A 90 day repeated dose toxicity study in dogs fed with analogue 2 in the diet at 0, 20, 40 and 60 mg/kg bw/day recorded no changes apart from a transient decrease in food intake in both sexes in the high-dose group (60 mg/kg bw/day) for the first few weeks. Based on the this information, together with the expected limited potential for absorption of the notified polymer across biological membranes, the potential for the notified polymer to cause systemic toxicity from repeated exposure is expected to be low.

Mutagenicity/Genotoxicity.
Analogue 1 was found to not be mutagenic using a bacterial reverse mutation test; however, it is noted that appropriate positive controls were not used. Analogue 1 was not genotoxic in an *in vivo* mouse micronucleus test. Only one of the mice treated with analogue 1 exhibited a statistically significant depression of PCE/(PCE+NCE) ratio after 24 hours. No clinical signs of toxicity or additional reductions in the PCE/(PCE+NCE) ratio (cytotoxicity) were observed with the analogue treatment. It is therefore not known if the analogue reached the bone marrow. Based on the available information, the notified polymer is not expected to be genotoxic.

Health hazard classification
Based on the available information, the notified polymer is 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. The recommended hazard classification is presented in the following table.

Hazard classification	***Hazard statement***
Skin sensitisation (Category 1)	H317: May cause an allergic skin reaction

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R43: May cause sensitisation by skin contact

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Dermal and ocular exposure to the notified polymer, at concentrations up to 100%, by workers may occur during the manufacture of the polymer, reformulation of it into resins and the use of these resins to manufacture articles. Once the notified polymer is reformulated into articles, the notified polymer will be incorporated into a polymer matrix and hence will not be bioavailable. Toxicological studies on the notified polymer indicate that it may be a skin sensitiser and hence its use is only considered to be reasonable when sufficient engineering controls, safe work practices and personal protective equipment (PPE) are used to greatly reduce the potential for exposure. Dermal exposure is expected to be limited, due to personal protective equipment (gloves, coveralls and safety glasses/goggles).

Where there may be worker exposure to partly cured resins, precautions to avoid sensitisation should be applied, similar to those for the notified polymer itself. Once the resin is completely cured, in sanitary ware articles, it is not expected to be bioavailable. Therefore, given the use of sufficient workplace controls, the risk to workers from use of the notified polymer is not considered unreasonable.

6.3.2. Public Health

The notified polymer will only be available to the public when present in articles, where it will be bound within a polymer matrix and hence will not be bioavailable. Therefore the risk to the 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 notified polymer will be both manufactured and imported into Australia. The notified polymer will be manufactured in a reactor. Equipment used in the production and packaging of the notified polymer will be cleaned by flushing with solvent. The resulting dispersion of solvent and notified polymer will be transferred to settling tanks where the notified polymer precipitates to form a sludge which is collected and dispatched to a trade waste facility for disposal to landfill. Up to 0.5% of the total introduction volume of notified polymer may be disposed to landfill annually during its manufacture. The notified polymer will be reformulated with other additives to produce finished resins. Equipment used to reformulate the notified polymer will be flushed with solvent as for manufacturing equipment. Up to 0.35% of the notified polymer is expected to be disposed of annually to landfill via this route. Accidental spills of notified polymer during manufacture and reformulation are not expected to be significant and are expected to be collected properly for disposal to landfill.

RELEASE OF CHEMICAL FROM USE

Following composite fabrication processes the notified polymer will be entrapped within a hardened matrix where it is considered immobile and inert. No release of the notified polymer from end use is predicted when present in this state. Up to 0.5% of the notified polymer is expected to be disposed of to landfill due to the cleaning of fabricating equipment.

RELEASE OF CHEMICAL FROM DISPOSAL

It is expected that up to 1.5% of both imported and manufactured volume of the notified polymer may be released annually to landfill as wastes generated from manufacturing/reformulation/fabrication and cleaning equipment.

7.1.2. Environmental Fate

The notified polymer is not expected to be readily biodegradable based on its chemical structure. Most of the notified polymer is expected to be associated with sanitary ware products and share the fate of the products. Disposal to landfill is expected to be the most likely fate of the used products and the associated notified polymer. A small amount of the notified polymer is expected to be sent to landfill as collected waste from manufacturing, reformulation and fabrication processes. The notified polymer waste disposed to landfill is not expected to leach given the expected low water solubility. In landfill, the polymer is expected to undergo slow abiotic and/or biotic degradation processes eventually to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

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

7.2. Environmental Effects Assessment

No ecotoxicological data were submitted for the notified polymer. The results from ecotoxicological investigations conducted on a close analogue of the notified polymer (analogue 1) are summarised in the table below. Analogue 1 and the notified polymer are considered to be very similar in chemical composition and physico-chemical properties and therefore the endpoints presented below are likely to reflect the ecotoxicity of the notified polymer. Details of the studies of analogue 1 can be found in Appendix B.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 h)	LL50 = 97.6 mg/L (filtered WAF)*	Expected to be harmful to fish
Daphnia Toxicity (48 h)	EL50 = 59.8 mg/L (filtered WAF)*	Expected to be harmful to aquatic invertebrates
Algal Toxicity (96 h)	E_rL50 = 259 mg/L (filtered WAF)*	Not expected to be harmful to algae

*WAF: Water Accommodated Fraction

The notified polymer is expected to be harmful to fish and aquatic invertebrates, but is not expected to be harmful to algae. On the basis of the acute toxicity data of analogue 1, the notified polymer is expected to be harmful to aquatic organisms. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified polymer is formally classified as 'Acute Category 3; Harmful to aquatic life' under the GHS. Based on the acute toxicity data and the lack of ready biodegradability, the notified polymer is formally classified as 'Chronic Category 3; Harmful to aquatic life with long lasting effects' under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) was not calculated since no significant release of the notified polymer is expected based on the proposed use pattern.

7.3. Environmental Risk Assessment

The Risk Quotient (RQ = PEC/PNEC) was not calculated since the PEC was not available for the calculation. The notified polymer is not expected to pose an unreasonable risk to the environment based on the assessed use pattern indicating limited release to the environment and expected low ecotoxicity to aquatic organisms.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – dermal

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 402 Acute Dermal Toxicity.
Species/Strain	Rat/ Sprague Dawley
Vehicle	Acetone
Type of dressing	Semi-occlusive.
Remarks - Method	Animals were observed at 1-, 3- and 5-hours after administration and then at least once daily for 7 days.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
control	1 per sex	0	0/2
low dose	1 per sex	200	0/2
mid dose	1 per sex	1000	0/2
high dose	1 per sex	2000	0/2

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	No evidence of test substance-related dermal reactions.
Signs of Toxicity - Systemic	No clinical signs were observed.
Effects in Organs	No abnormalities were noted at necroscopy
Remarks - Results	No effect on body weight was observed during the study.

CONCLUSION Analogue 1 is of low toxicity via the dermal route.

TEST FACILITY ICP Firefly (2013a)

A.2. Acute toxicity – dermal

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 402 Acute Dermal Toxicity.
Species/Strain	Rat/ Sprague Dawley
Vehicle	Test substance administered as supplied
Type of dressing	Semi-occlusive.
Remarks - Method	Observations were recorded at 1-, 2- and 4-hours and then daily for 14 days.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5M/5F	2000	0/10

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	No evidence of test substance-related dermal reactions.
Signs of Toxicity - Systemic	No clinical signs were observed.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks - Results	No weight loss was observed in any animal, and comparable weight gain was observed between the groups.

CONCLUSION Analogue 1 is of low toxicity via the dermal route.

TEST FACILITY ICP Firefly (2013b)

A.3. Irritation – skin

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (F)
Vehicle	Test substance administered as supplied
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations.
RESULTS	
Remarks - Results	No signs of erythema or oedema were observed for any of the animals during the study period.
CONCLUSION	Analogue 1 is non-irritating to the skin.
TEST FACILITY	ICP Firefly (2013c)

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

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/(SPF) CBA/CaH
Vehicle	Acetone/ Olive Oil (4:1 v/v))
Remarks - Method	No significant protocol deviations. Groups each contained 5 female mice. The positive control used was α-hexylcinnamaldehyde (HCA).

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	437	1
25	882	2
50	2899	6.6
100	2173	5
Positive Control		
25 % HCA	4160	9.5

Remarks - Results	No mortality was observed. No clinically significant body weight differences were observed. No obvious signs of toxicity, erythema, oedema or other findings were observed in any of the animals. The mean DPM result for each group was recorded in the table. The stimulation index (SI) for the medium and high dose test groups was above 3 and hence the notified polymer is considered to be a potential skin sensitiser. The test item sensitisation potential (EC3) was calculated to be 30.43%. The positive control confirmed the sensitivity of the test system.
CONCLUSION	There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to analogue 1.
TEST FACILITY	ICP Firefly (2013d)

A.5. Genotoxicity – bacteria

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation method.
Species/Strain	*S. typhimurium*: TA98, TA100, TA102, TA1535, TA1537
Metabolic Activation System	Rat liver microsomal enzymes and cofactors, S9 mix
Concentration Range in Main Test	a) With metabolic activation: 31.6 - 5000 µg/plate b) Without metabolic activation: 31.6 - 5000 µg/plate
Vehicle	Dimethylsulfoxide
Remarks - Method	2-Aminoanthracene was used as the positive control both in the presence and absence of metabolic activation.

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	> 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	Precipitation of the test substance was noted in the preliminary study at concentrations of 2,500 and 5000 µg/plate. No evidence of toxicity was observed in the preliminary test. The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of metabolic activation. Negative controls were within historical limits, or lower. Positive controls confirmed the sensitivity of the test system in the presence of metabolic activation. However, in the absence of metabolic activation the positive control failed to induce a sufficient increase in the mean number of revertants in any of the bacterial strains tested. According to the OECD TG 471 (1997) while 2-aminoanthracene is recommended for assays performed with metabolic activation it is not listed as an appropriate positive control when metabolic activation is not present. Therefore, although there was no evidence that the test substance would be mutagenic to bacteria in the absence of metabolic activation the lack of a suitable positive control means that this part of the assay cannot be validated.
CONCLUSION	Analogue 1 was not mutagenic to bacteria under the conditions of the test, noting the limitations of the methodology.
TEST FACILITY	ICP Firefly (2013e)

A.6. Genotoxicity – in vivo

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mouse/Arc(S) Swiss
Route of Administration	Dermal – semi-occluded
Vehicle	Test substance administered as supplied
Remarks - Method	A preliminary toxicity study was carried out using 2 male and 2 female mice dosed with the test substance at 2000 mg/kg bw. No mortalities were

observed.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5 per sex	0	24
II (vehicle control)	5 per sex	0	48
III (positive control*)	5 per sex	40	48
IV (test substance)	5 per sex	2000	24
V (test substance)	5 per sex	2000	48

*The positive control used was 7,12-dimethylbenz[a]anthracene (DMBA)

RESULTS

Doses Producing Toxicity

No clinical abnormalities were observed in the negative control or treated animals during the test period. Animals in the positive control group dosed intraperitonially lost weight due to toxicity of DMBA.

Genotoxic Effects

The test substance induced no statistically significant increases in micronucleated, polychromatic erythrocytes (PCEs) at either sampling time.

The positive control caused a significant increase in the number of micronucleated immature erythrocytes, demonstrating the sensitivity of the test.

Remarks - Results

One of the female mice treated with the test item exhibited a statistically significant depression of PCE/(PCE+NCE) ratio after 24 hours. All other mice exhibited ratios similar to those observed for the negative control groups, so this result may be considered as an independent event.

No clinical signs of toxicity or reductions in the PCE/NCE ratio (cytotoxicity) were observed in animals treated with the test substance, so it is therefore not known if the test substance reached the bone marrow.

CONCLUSION

Analogue 1 was not clastogenic under the conditions of this *in vivo* mouse micronucleus test.

TEST FACILITY

ICP Firefly (2013f)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1 Ecotoxicological Investigations

B.1.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi-static Test
Species	Zebra Fish (*Danio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	Not reported
Water Hardness	10 - 250mg $CaCO_3$/L
Analytical Monitoring	LCMS-MS (Liquid chromatography-tandem mass spectrometry)
Remarks – Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. The fish ecotoxicity test was conducted in Water Accommodated Fractions (WAFs) of the analogue chemical as it is a complex mixture and has low water solubility. WAFs of nominal loading rate were prepared by stirring the test substance in water by using a magnetic stirrer for 48 hours. WAF treatment solutions were filtered using 3.1 µm filter paper prior to use in the experiment.

Results

Nominal Concentration (mg/L)	Number of Fish	Cumulative mortality (%)				
		3 h	24 h	48 h	72 h	96 h
Control	7	0	0	0	0	0
31.8	7	0	0	0	0	0
63	7	0	0	0	0	14.3
125	7	0	0	14.3	57.1	71.4
251	7	0	0	71.4	100	100
513	7	0	100	100	100	100

LL50	97.6 (66.9 – 143.5) mg/L at 96 hours (filtered WAF)
NOEL	63 mg/L at 96 hours (filtered WAF)
Remarks – Results	All validity criteria for the test were satisfied. The concentrations of the test substance for all treatments were measured at 0 and 48 hours within the 96-h test period. The treatment solutions were renewed at 48 h test period. The concentrations of the test substance at all treatment levels were found to be within 20% of the initial concentration from the start to end of the 48 h renewal period. Therefore, it is expected that the endpoints were calculated based on the nominal loading rate. The 96 h LL50 and the confidence interval were calculated by Probit analysis using Linear Maximum Likelihood method. NOEL value was calculated using Fisher's Exact Binomial Test with Bonferroni Correction.
CONCLUSION	Analogue 1 is harmful to fish
TEST FACILITY	ICP (2013g)

B.1.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Static Test
Species	*Daphnia carinata*
Exposure Period	48 hours
Auxiliary Solvent	None reported
Water Hardness	10 - 250mg $CaCO_3$/L
Analytical Monitoring	LCMS-MS (Liquid chromatography-tandem mass spectrometry)
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. The daphnia ecotoxicity test was conducted in Water Accommodated Fractions (WAFs) of the analogue chemical as it is a complex mixture and has low water solubility. WAFs of nominal loading rate were prepared by stirring the test substance in water by using a magnetic stirrer for 48 hours. WAF treatment solutions were filtered using 3.1 µm filter paper prior to use in the experiment.

RESULTS

Concentration (mg/L)		Number of D. carinata	Cumulative % Immobilised	
Nominal	Mean measured (0 h)		24 h	48 h
0	0	20	0	0
32	20	20	0	40
62	65	20	0	50
129	146	20	0	60
252	230	20	15	85
505	347	20	20	100

EL50	59.8 (33.0 –87.0) mg/L at 48 hours (filtered WAF)
NOEL	< 33mg/L at 48 hours (filtered WAF)
Remarks - Results	All validity criteria for the test were satisfied. The concentrations of the test substance for all treatments were measured at the beginning and end of the test. The concentrations of the test substance at all treatment levels were found to be within 20% of the initial concentration from the start to end of the end of the 48 h test period. Therefore, endpoints were calculated based on the nominal loading rate. The 48 h EL50 and the confidence interval were calculated by Probit analysis using Linear Maximum Likelihood method. NOEL value was calculated using Fisher's Exact Binomial Test with Bonferroni Correction.
CONCLUSION	Analogue 1 is harmful to aquatic invertebrates
TEST FACILITY	ICP (2013h)

B.1.3. Algal growth inhibition test

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 15, 31, 63, 129, and 258 mg/L
Auxiliary Solvent	Not reported
Water Hardness	Not reported
Analytical Monitoring	LCMS-MS (Liquid chromatography-tandem mass spectrometry)
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. The algae ecotoxicity test was conducted in Water Accommodated Fractions (WAFs) of the analogue chemical as it is a complex mixture and has low water solubility. WAFs of nominal loading rate were prepared by stirring the test substance in water by using a magnetic stirrer for 48 hours. WAF treatment solutions were filtered using 3.1 µm filter paper prior to use in the experiment.

RESULTS

Biomass (72 h)		*Growth (72 h)*	
E_yL50 (mg/L)	*NOE_yL (mg/L)*	*E_rL50 (mg/L)*	*NOE_rL (mg/L)*
80 (60.5 – 121)	15	259 (214 – 357)	15

Remarks - Results	All validity criteria for the test were satisfied. The concentrations of the test substance for all treatments were measured at the beginning and end of the test. The concentrations of the test substance at all treatment levels were found to be within 20% of the initial concentration from the start to end of the end of the 72 h test period. Therefore, endpoints were calculated based on the nominal loading rate. The 72 h E_rL50 and the confidence interval were calculated by Probit analysis using Linear Maximum Likelihood method. NOE_rL value was calculated using Fisher's Exact Binomial Test with Bonferroni Correction.
CONCLUSION	Analogue 1 is not harmful to algae.
TEST FACILITY	ICP (2013i)

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