File No: LTD/1828

June 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in IDN7126a

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

TABLE OF CONTENTS

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1828	IMCD Australia Limited	Polymer in IDN7126a	ND*	≤ 400 tonnes per annum	Component of lubricant oil

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment
On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Coveralls, impervious gloves, safety goggles

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

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

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- the polymer has a number-average molecular weight of less than 1000;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of lubricant oil, 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.

(Material) Safety Data Sheet
The (M)SDS of a product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
IMCD Australia Limited (ABN: 44 000 005 578)
First floor, 372 Wellington Road
MULGRAVE VIC 3170

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, import volume 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: all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China (2012), Japan (2014), Korea (2014) and Philippines (2012)

2. IDENTITY OF CHEMICAL

MARKETING NAME
IDN7126a

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference GPC and FTIR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Brown liquid

Property	Value	Data Source/Justification
Glass Transition Temperature	16 – 25 °C	Analogue data
Boiling Point	> 350 °C at 101.3 kPa	Analogue data. The polymer decomposes before boiling
Relative Density	0.967 ± 0.001	Analogue data
Vapour Pressure	4.5×10^{-14} kPa at 20 °C 9.5×10^{-14} kPa at 25 °C	Analogue data
Water Solubility	$< 1 \times 10^{-4}$ g/L at 20 °C	Analogue data
Organic Solvent Solubility at 20 °C	> 250 g/L in n-Heptane > 250 g/L in 1,2-Dichloroethane > 250 g/L in Acetone > 250 g/L in p-Xylene > 250 g/L in Ethyl acetate	Analogue data
Hydrolysis as a Function of pH	Not determined	Contains no hydrolysable functionalities

Partition Coefficient (n-octanol/water)	log Pow ≥ 7 at 20 °C	Analogue data
Adsorption/Desorption	Not determined	Expected to adsorb strongly to soil and sediment
Dissociation Constant	Not determined	Expected to be ionised under environmental pH (4-9)
Flash Point	170 °C	(M)SDS
Flammability	Not flammable	Analogue data
Autoignition Temperature	> 430 °C	Analogue data
Explosive Properties	Non explosive	Analogue data
Oxidising Properties	Non oxidizing	Analogue data

DISCUSSION OF PROPERTIES
No study reports on the notified polymer were provided. Physico-chemical property studies conducted on analogue with a similar structure were provided to fill the data gap. For full details of tests on physical and chemical properties on analogue, refer to Appendix A.

Reactivity
Based on the analogue data, the notified polymer is expected to be stable under normal conditions of use.

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

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured within Australia. The notified polymer will be imported into Australia a component of lubricant additive packages (< 50 % concentration) for reformulation or in finished lubricating oil (< 10 % concentration) for end-use.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 400	< 400	< 400	< 400	< 400

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
Lubricant additive packages and finished lubricating oils will be imported in 205 L drums or bulk containers. The containers will be transported by road to the consumer site for reformulation/repackage and/or the warehouse for storage.

USE
The notified polymer will be used in lubricating oil at < 10% concentration for marine industrial applications.

OPERATION DESCRIPTION
The notified chemical will not be manufactured in Australia, but the lubricant additive packages will be reformulated after importation.

Reformulation
Imported lubricant additive packages containing the notified polymer (at < 50%) will be transferred into storage tanks through hoses with air back flush systems to prevent spillage, before being transferred into the blending facilities and formulated into lubricating oil products by mixing with other additives. Transfer from the storage tanks to the blending facilities and the blending process itself is expected to involve automated, well ventilated and enclosed systems. Samples may be collected at various stages for quality control. The finished lubricating oil containing the notified polymer at < 10 % concentration will be repackaged via an automated system.

End use
The lubricating oil containing the notified polymer at < 10 % concentration will be transported to ports and then to lubricant storage containers on ships using automated systems where it will be pumped from the container into the engine as required.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	1	30-60
Blending operators	2	50-100
Quality control technician	1	50-100
Packaging workers	2	50-100
Engine operators	1	100-200

EXPOSURE DETAILS
Transport and storage workers are not expected to be exposed to the notified polymer (at < 50 % concentration) except in the unlikely event of an accidental release due to container breach or spill.

Dermal and ocular exposure of workers to the notified polymer at up 50% concentration may occur during transfer, mixing, quality control testing and equipment cleaning and maintenance. The blending process itself is expected to be automated and within a closed system.

Packaging workers and engine operators may be exposed to lubricating oil containing up to 10% of the notified polymer during packaging and during transfer to lubricant storage containers on ships. Due to the low vapour pressure (9.5×10^{-14} kPa at 25 °C) inhalation exposure is not expected.

Exposure to the notified polymer is expected to be minimised by use of personal protective equipment (PPE) including impervious gloves, coveralls, safety goggles and boots as anticipated by the notifier in the application dossier. In addition the processes will be carried out under good general ventilation conditions and the transfer pipelines will be cleaned either with mineral oil or air/nitrogen blown to remove residual product before disconnecting the lines.

6.1.2. Public Exposure
The notified polymer is intended for use in industry only. Public exposure to the notified polymer is not expected except in the unlikely event of an accident occurring during road transport. Exposure to the public is therefore expected to be negligible.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer and an analogue 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*	LD_{50} > 2,000 mg/kg bw; low toxicity
Rat, repeat dose oral toxicity – 14 days	NOAEL 1,000 mg/kg bw/day
Rat, repeat dose oral toxicity – 28 days	NOAEL 1,000 mg/kg bw/day
Rat, repeated dose oral toxicity – 28 days*	NOAEL 1,000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration test	non genotoxic

'*' – Analogue data

Toxicokinetics, metabolism and distribution.
No toxicokinetics, metabolism and distribution studies were submitted for the notified polymer. For dermal absorption, molecular weights below 500 Da are favourable for absorption and molecular weights above 1,000

Da do not favour absorption (ECHA, 2012). Dermal uptake is likely to be low if the water solubility is below 1 mg/L and the rate of penetration may be limited by the rate of transfer between the stratum corneum and the epidermis if log P values are above 4 (ECHA, 2012). Based on the high molecular weight (> 1,000 Da), the estimated low water solubility (< 1×10^{-4} g/L; analogue data) and high partition coefficient (log Pow ≥ 7; analogue data) dermal absorption of the notified polymer is expected to be very low.

Acute toxicity.
No acute toxicity studies were submitted for the notified polymer. An acute oral toxicity study conducted on an analogue showed it to be of low toxicity via the oral route.

Irritation and sensitisation.
No irritation and sensitisation studies were submitted for the notified polymer.

Repeated dose toxicity.
A 14-day repeated dose oral toxicity study and a 28-day repeated dose oral toxicity study with a 14-day recovery were submitted for the notified polymer. The 14-day and 28-day studies conducted used the notified polymer at 100, 300 and 1,000 mg/kg bw/day concentrations, with the study authors considering there to be no treatment related adverse effects.

A 28-day repeated dose toxicity study was also submitted on an analogue. Similarly a NOAEL of 1,000 mg/kg bw/day was reported for the analogue again based on an absence of treatment related effects at the highest dose level (WIL 2005b).

Mutagenicity/Genotoxicity.
The notified polymer was not mutagenic in an in vitro bacterial reverse mutation test or clastogenic in an in vitro chromosome aberration test using human peripheral blood lymphocytes.

Health hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of 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
Based on the studies conducted on the notified polymer and analogue, the notified polymer is anticipated to be of low toxicity. There is a potential for dermal and perhaps ocular exposure of workers to the notified polymer at up to 50% concentration during reformulation, blending equipment cleaning and maintenance and at up to 10% concentration during transfer of lubricating oil to lubricant storage containers on ships. The notifier anticipated use of PPE such as goggles, coveralls and impervious gloves along with automated and enclosed processes should minimise the exposure.

Overall, given the low toxicity of the notified polymer and the proposed controls, the risk to the health of workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health
The public is not expected to be exposed to the notified polymer except in an event of an accident during road transport; hence 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 manufactured overseas, and will be imported as a component of lubricant additive packages at < 50% concentration that will be reformulated locally into finished lubricants, predominantly for marine applications. No significant release is expected from the transportation and storage of the products containing the notified polymer.

Local blending or repackaging will be performed in an enclosed automated system; therefore, spills from reformulation are expected to be minimal. It is expected that any incidental terrestrial spillage of the additive package containing the notified polymer that occurs during normal blending procedures will be contained with sand or earth, before being transported off-site to an approved industrial facility for treatment. Any aquatic spillage of the additive package containing the notified polymer is expected to be contained with adsorbents and then collected for appropriate disposal. Empty containers, transfer hoses, pipelines, and pumps are expected to be air/nitrogen blown dry, and/or cleaned by flushing through with mineral-based oil. Waste oil generated from cleaning is expected to be disposed of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE
Marine lubricants containing the notified polymer will be pumped into marine engines, which are closed systems, by professional personnel in industrial settings. Release of the notified polymer from professional activities is expected to be limited by the requirement for appropriate disposal of waste oils according to State/Territory regulations. As an additive in lubricant oils for marine engines, the majority of the notified polymer will be consumed and thermally decomposed during use.

RELEASE OF CHEMICAL FROM DISPOSAL
Products containing the notified polymer and container wastes are expected to be disposed of in accordance with State/Territory regulations. Consequently, the majority of the notified polymer is expected to be disposed of by thermal treatment.

7.1.2. Environmental Fate
The majority of the notified polymer in marine engine oils will be consumed and thermally decomposed during use.

The majority of the notified polymer in collected waste is expected to be disposed of by thermal treatment in accordance with local government regulations. Minor amounts of the notified polymer are expected to be disposed of to landfill as residues in containers or collected waste. Given that the notified polymer is expected to adsorb strongly to soils based on its high molecular weight, low water solubility, and high partition coefficient ($\log P_{OW} \geq 7$), the notified polymer sent to landfill is expected to be immobile.

A study submitted by the notifier indicates that the notified polymer is not expected to be readily biodegradable (≤ 1% in 28 days). However, based on its high molecular weight and low water solubility, as well as its limited expected release to the aquatic environment, the notified polymer is not expected to be bioaccumulative or be bioavailable, as it is not expected to cross biological membranes. In landfill, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon. Details of the environmental fate studies can be found in Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)
The notifier expects that 100% of the notified polymer will be used in marine lubricants, and that products containing the notified polymer will not be available to DIY end-users. Therefore, the notified polymer is not anticipated to be released to the aquatic environment through improper disposal by DIY end-users. Release of the notified polymer to the marine environment through leakages and spills is not expected under normal operating conditions. Therefore, the predicted environmental concentration (PEC) has not been calculated, since no significant release of the notified polymer to the aquatic environment is expected from 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. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LL50 > 100 mg/L (WAF*)	Not harmful to fish up to limit of water solubility
Daphnia Toxicity	96 h LL50 > 100 mg/L (WAF*)	Not harmful to *Daphnia* up to limit of water solubility
Algal Toxicity	96 h LL50 > 100 mg/L (WAF*)	Not harmful to algae up to limit of water solubility

* Water Accommodated Fraction

Based on the above ecotoxicological endpoints for the notified polymer, it is not considered to be harmful to fish, daphnids, and algae up to the limit of its solubility in water. Therefore, under the *Globally Harmonised*

System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified polymer is not formally classified for acute and chronic toxicities.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated since the notified polymer is not considered to be harmful to aquatic organisms up to the limit of its solubility in water, and no significant release of the notified polymer to the aquatic environment is expected.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) of the notified polymer has not been calculated as neither the PEC nor PNEC are available, and due to its low potential for release to the aquatic compartment. The majority of the notified polymer will be thermally decomposed during use as a lubricant additive in marine engine oils. The majority of engine oil containing the notified polymer, after its useful life, is expected to be disposed of according to State/Territory regulations. The notified polymer in waste oils sent to landfill is expected to adsorb strongly to soil and sediment, based on its high molecular weight, low water solubility, and high log P_{OW}. Release of the notified polymer to the aquatic compartment is unlikely based on the reported use pattern. On the basis of its limited aquatic exposure and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Glass Transition Temperature 16 – 25 °C

Method OECD TG 102 Melting Point/Melting Range.
Remarks The thermal behaviour of test substance was assessed by differential scanning calorimetry
Test Facility Covance (2005)

Boiling Point > 350 °C at 101.3 kPa

Method OECD TG 103 Boiling Point.
Remarks The thermal behaviour of test substance was assessed by differential scanning calorimetry. The boiling point could not be determined due to decomposition at 350 °C
Test Facility Covance (2005)

Relative Density 0.967 ± 0.001

Method OECD TG 109 Density of Liquids and Solids.
Remarks Pyknometer method.
Test Facility Covance (2005)

Vapour Pressure 4.5×10^{-14} kPa at 20 °C and 9.5×10^{-14} kPa at 25 °C

Method OECD TG 104 Vapour Pressure.
Remarks Knudsen Effusion method.
Test Facility Covance (2005)

Water Solubility $< 1 \times 10^{-4}$ g/L at 20 °C

Method OECD TG 105 Water Solubility.
Remarks Shake flask method
Test Facility Covance (2005)

Organic Solvent Solubility
> 250 g/L in n-Heptane at 20 °C
> 250 g/L in 1,2-Dichloroethane at 20 °C
> 250 g/L in Acetone at 20 °C
> 250 g/L in p-Xylene at 20 °C
> 250 g/L in Ethyl acetate at 20 °C

Method Collaborative International Pesticides Analytical Council (CIPAC) – Method MT 181 Solubility in Organic Solvents
Remarks The solubility of test substance was determined by a non-analytical, preliminary and refined solvent addition procedure.
Test Facility Covance (2005)

Partition Coefficient(n-octanol/water) log Pow ≥ 7 at 20 °C

Method OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks Estimated as a ratio between solubility in n-octanol and solubility in water.
Test Facility Covance (2005)

Flammability Not flammable

Method EC Council Regulation No 92/69 A.10 Flammability (Solids).
Remarks The test substance was heated till it melted to an amber colour liquid. No flames/sparks/smoke was seen.
Test Facility Covance (2005)

Autoignition Temperature > 430 °C

Method	EC Council Regulation No 92/69 A.16 Relative Self-Ignition Temperature for Solids.
Remarks	On heating the test substance to 430 °C, no self-ignition was observed.
Test Facility	Covance (2005)

Explosive Properties Non explosive

Method	EC Council Regulation No 92/69 A.14 Explosive Properties.
Remarks	Observation of functional groups that would imply explosive properties and differential scanning calorimetry. The calculated oxygen balance was -303%.
Test Facility	Covance (2005)

Oxidizing Properties Non oxidizing

Method	EC Council Regulation No 92/69 A.17 Oxidizing Properties (Solids).
Remarks	The notified polymer was mixed with cellulose and compared to a barium nitrite positive control. At concentrations above 10% the notified polymer inhibited the ability of the cellulose mixture to burn.
Test Facility	Covance (2005)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Analogue
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Crl:CD(SD)
Vehicle	Corn oil
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
A	3 female	300	0/3
B	3 female	300	0/3
C	3 female	2,000	0/3
D	3 female	2,000	0/3

LD50	> 2,000 mg/kg bw
Signs of Toxicity	There were no unscheduled deaths. Clinical findings included abnormal excretion, various discoloured areas due to discharge/excretions, hair loss, dermal atonia and thinness.
Effects in Organs	No macroscopic findings were recorded at necropsy.
Remarks - Results	The body weights of the animals were within the normal range for the age and no reductions were recorded during the observation period.
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	WIL (2005a)

B.2. Repeat dose toxicity – 14 Days

TEST SUBSTANCE	Notified chemical
METHOD	14-Day Range Finding Repeated Dose Oral Toxicity Study in Rodents
Species/Strain	Rats / Hsd:SD
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 14 days Dose regimen: 7 days per week Dose Volume: 10 mL/kg
Vehicle	Corn Oil
Remarks - Method	The method used was similar to OECD TG 407 for 28-day repeated dose toxicity studies. All animals were observed twice daily at least 6 hours apart for moribundity and mortality. All animals were observed daily (cage side observation) for clinical signs of toxicity within two hours after the last animal dosed in each group. Detailed hand-on observations were performed on study days 1, 8 and 15. Body weights of individual animals were recorded prior to randomization and prior to dosing on day 1, 8 and 15. Full necropsy of all surviving study animals was performed after the terminal sacrifice. No organs were weighed and no tissues were collected or preserved.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*

control	5 F & 5 M	0	0/10
low dose	5 F & 5 M	100	0/10
mid dose	5 F & 5 M	300	0/10
high dose	5 F & 5 M	1,000	0/10

Mortality and Time to Death
No deaths reported during treatment.

Clinical Observations
No clinical signs of toxicity were noted in any animals during the daily cage side observations and weekly hands-on observations in any test groups.
Males from low dose group had statistically significant increase in mean body weight on day 15 & significantly higher body weight gains in weeks 1 & 2. Males from mid dose group had higher mean body weight gains in week 1. Females from mid dose group had significantly lower mean body weight gains in week 1.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No laboratory tests were conducted.

Effects in Organs
Discoloration of the kidneys (bilateral) was noted in rats of both sexes in all dose groups including the control. The incidence of discoloration tended to increase with the dose level with 3, 3, 4 and 5 in males and 1, 4, 3 and 5 in females of groups 1 through 4 respectively. Kidney nodules were noted bilaterally in one male from the low dose group.

Remarks – Results
The significant changes in body weights and weight gains observed were attributed to individual animal variability and small group size by the study author due to the lack of a dose-effect relationship.
Due to no histopathology studies conducted on animals, a clear relationship between the effects on kidneys and the test substance could not be established by the study authors.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1,000 mg/kg bw/day in this study, based on the determination by the study author of an absence of test substance related effects at all doses.

TEST FACILITY BioReliance (2012a)

B.3. Repeat dose toxicity – 28 Days

TEST SUBSTANCE Notified chemical

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

Species/Strain	Rat/Crl:CD®(SD)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Dose volume: 10 mL/kg Post-exposure observation period: 14 days
Vehicle	Corn oil
Remarks - Method	No significant protocol deviations. The study also evaluated the potential for neurotoxicity by Functional Observational Battery (FOB) and locomotor activity assessments. The study was conducted in 2 phases due to the unscheduled deaths of 2 animals from the control group and 6 animals from the high dose groups.

RESULTS

Phase I

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
Control	10 F & 10 M	0	1/20

low dose	10 F & 10 M	100	2/20
mid dose	10 F & 10 M	300	0/20
high dose	10 F & 10 M	1,000	4/20
control recovery	5 M & 5 F	0	1/10
high dose recovery	5 M & 5 F	1,000	2/10

Phase II

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
Control	7 F & 7 M	0	0/14
high dose	7 F & 7 M	1,000	0/14
control recovery	5 F & 5 M	0	0/10
high dose recovery	5 F & 5 M	1,000	1/10

Mortality and Time to Death

Phase I

During week 2, 5 males from the high dose, 2 females from the control, 2 females from the low dose and 1 female from the high dose groups were either found dead or sacrificed due to moribundity. The cause of death was gavage accident in 5 cases from high dose group and was undetermined in other cases. Due to high mortality, the control and high dose groups were repeated again in phase II of the study.

Phase II

One female rat from high dose group was found dead on day 13. The cause of death was undetermined.

Clinical Observations

Phase I

Daily cage side observations – In males, decreased motor activity, laboured breathing and discharge from mouth were observed in some of the early death animals from high dose group. Other males from the high dose group exhibited hunched posture, ruffled fur, laboured or rapid and shallow breathing. In females, hunched posture, ruffled fur and thinness were noted in 1-2 animals in the groups treated with the test substance. Other signs of toxicity noted sporadically in female rats included a comatose state, hypothermia, decreased motor activity, laboured or rapid and shallow breathing and prostrate posture.

Weekly hands-on observations – One male rat from the high dose group was observed to be thin. 4 females from the high dose group exhibited thinness, ruffled fur, laboured or rapid and shallow breathing. The clinical signs were also exhibited sporadically in females from low and medium dose test groups.

FOB assessment – Vocalization was observed during hands-on assessment in animals from all test groups including control. Repeated rearing was noted in males and rapid respiration, shallow breathing, hypokinetic or hyperkinetic movement was noted in females from test and control groups. No test substance related changes were noted in open field, elicited and numerical observations.

Body weight and food consumption – There were no statistically significant differences in body weights and body weight gains between the control and treatment groups. A statistically significant decrease in food consumption in high dose males in the first week of recovery was considered to be incidental by the study authors.

Phase II

Daily cage side observations – No clinical signs were noted.

Weekly hands-on observations – No clinical signs were noted.

FOB assessment – Vocalization and / or nasal discharge were noted sporadically in males from both test and control groups during hands-on FOB assessment. No test substance related changes were noted in open field, elicited and numerical observations.

Body weight and food consumption – There were statistically significant fluctuations in male body weight gains, but these had no effect on the overall bodyweight and were therefore considered to be incidental to treatment with the test article. There were no effects on female body weight or body weight gains or on food consumption in either sex.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

All the animals designated for necropsy were sampled for haematology, serum chemistry, coagulation and urinalysis.

Phase I

Slight but significant decrease in urea nitrogen, calculated globulin and total protein were noted in rats from the high dose group. Slight but significant decrease in mean cholesterol levels were observed in rats from the low, mid and high dose groups. No changes were observed in the high dose recovery group. No test item related changes in haematology, coagulation and urinalysis were noted.

Phase II

Inorganic phosphorous levels were significantly lower in the high dose non-recovery and recovery group rats compared to the control group. No other significant test article related haematological, coagulation, serum chemistry and urinalysis changes were noted.

Effects in Organs

Phase I

Significant increase in absolute mean heart (10.9%), liver (14.2%) and thyroid/parathyroid (19.6%) weights were noted for male rats in low dose group. An increase in mean liver weight (12.7%) was observed in females rats from mid dose group. The organ weight increases were also reflected in relative organ weights across the test groups.

Phase II

Increase in mean relative liver weight (14.1%) was noted in male rats from high dose group. Increase in mean absolute kidneys weight and decrease in absolute spleen (13.5%) and prostate (13.2%) weight was observed in male rats from high dose group. The decrease in relative spleen weight (11.3%) and increase in kidneys weight (14.7%) persisted in high dose recovery group. No microscopic changes were noted in the organs.

Remarks – Results

The high level of mortality observed in high dose group in phase I of the study was attributed to gavage error and this was confirmed by Phase II study where only one animal died. The cause of death of this animal was undetermined as no toxicological changes were observed.

Clinical findings were considered by the study authors not to be test substance related due the random nature and presence in control groups.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1,000 mg/kg bw/day in this study, based on no adverse effects observed at the highest test dose concentration.

TEST FACILITY	BioReliance (2012b)

B.4. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction from Aroclor induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 1.5–5,000 µg/plate b) Without metabolic activation: 1.5–5,000 µg/plate
Vehicle	Acetone
Remarks - Method	No significant protocol deviations. 2-Nitrofluorene, sodium azide, 9-aminoacridine and methyl methanesulfonate were used as positive controls in absence of metabolic activation and 2-aminoanthracene was used as positive control in presence 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	> 5,000	> 5,000	≥ 500	Negative
Present	> 5,000	> 5,000	≥ 500	Negative

Remarks - Results: No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose, either with or without metabolic activation.
The positive controls produced satisfactory responses, thus confirming the activity of 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: Bioreliance (2012c)

B.5. Genotoxicity – in vitro

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain: Human
Cell Type/Cell Line: Peripheral blood lymphocytes
Metabolic Activation System: S9 fraction from Aroclor induced rat liver
Vehicle: Acetone
Remarks - Method: No significant protocol deviations. Vehicle and positive controls were carried out in parallel with test substance. Mytomycin C and cyclophosphamide were used as positive controls in absence and presence of metabolic activation, respectively.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	5, 10*, 15, 25*, 50*, 75	4 h	20 h
Test 2	5, 10*, 15, 25*, 50*, 75	20 h	20 h
Present			
Test 1	5, 10*, 15, 25*, 50*, 75	4 h	20 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	> 75	≥ 50	Negative
Test 2	> 5,000	> 75	≥ 50	Negative
Present				
Test 1	> 5,000	> 75	≥ 50	Negative

Remarks - Results: The positive controls showed increased mutation frequency, confirming the validity of the test system. The test substance did not induce any structural and numerical chromosome aberrations in absence and presence of metabolic activation.

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

TEST FACILITY: BioReliance (2012d)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	Japanese Industrial Standards (JIS) K 0102-2010 Section 14.1
Inoculum	Activated sludge from 10 locations in Japan, including surface waters, surface soils of rivers, lakes, and inland seas, and return sludge from sewage treatment plants.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biochemical Oxygen Demand (BOD)
Remarks - Method	No significant deviation in protocol.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	56
14	≤ 1	14	69
21	≤ 1	21	72
28	≤ 1	28	74

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound, aniline, surpassed the threshold level of 60% by 14 days (69%), and reached 74% degradation by 28 days. Therefore, the test indicates the suitability of the inoculums. The notified polymer attained ≤ 1% degradation by 28 days. Therefore, the notified polymer cannot be classified as readily biodegradable.
CONCLUSION	The notified polymer is not readily biodegradable.
TEST FACILITY	CERI (2011)

C.1.2. Ready biodegradability

TEST SUBSTANCE	Analogue
METHOD	OECD TG 301 C Ready Biodegradability: Manometric Respirometry, Modified MITI Test (I).
Inoculum	Activated sludge from 10 locations in UK, including sewage treatment plants with both industrial and domestic input, and from rivers, seas, and soils where a variety of chemicals are used and discharged.
Exposure Period	28 days
Auxiliary Solvent	Toluene
Analytical Monitoring	Theoretical Oxygen Demand (ThOD)
Remarks – Method	No significant deviation in protocol.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
5	< 5	5	37
9	< 5	9	37
15	< 5	15	37
21	< 5	21	37
28	< 5	28	37

Remarks – Results	The percentage degradation of the reference compound, sodium benzoate, did not reach the minimum 60% threshold (37%). Therefore, it was concluded that the test sludge did not contain sufficient viable organisms to degrade the reference compound and test substance.
CONCLUSION	The results of the study could not be verified.
TEST FACILITY	Brixham (2005a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 23 Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixture – Static.
Species	*Oryzias latipes* (medaka)
Exposure Period	96 hours
Auxiliary Solvent	Acetone
Water Hardness	39 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	No significant deviation in protocol

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	Control	7	0	0	0	0	0
100	< 0.49*	7	0	0	0	0	0

* Below limit of detection

LC50	> 100 mg/L (WAF) at 96 hours.
NOEC (or LOEC)	Not determined.
Remarks – Results	All validity criteria for the test were satisfied. The 96 h LL50 for fish was determined to be > 100 mg/L (WAF), based on the nominal loading concentration.
CONCLUSION	Under the study conditions, the notified polymer is not considered to be harmful to fish up to the limit of its water solubility.
TEST FACILITY	CERI (2013c)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 23 Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixture – Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Acetone
Water Hardness	39 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	No significant deviation in protocol

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*

Control	Control	20	0	0
100	< 0.495*	20	0	0

* Below limit of detection

EL50	> 100 mg/L (WAF) at 48 hours.
NOEC (or LOEC)	Not determined.
Remarks - Results	All validity criteria for the test were satisfied. The 48 h EL50 for daphnids was determined to be > 100 mg/L (WAF), based on the nominal loading concentration.

CONCLUSION Under the study conditions, the notified polymer is not considered to be harmful to daphnids up to the limit of its water solubility.

TEST FACILITY CERI (2013b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified polymer

METHOD OECD TG 23 Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixture – Static.

Species	*Psuedokirchneriella subcapitata* (green alga)
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L Actual: < 0.504 mg/L (limit of detection)
Auxiliary Solvent	Acetone
Water Hardness	Not reported
Analytical Monitoring	HPLC
Remarks - Method	No significant deviation in protocol

RESULTS

Biomass		*Growth*	
E_bL50	*NOE_bL*	*E_rL50*	*NOE_rL*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
Not determined	Not determined	> 100	≥ 100

Remarks - Results	All validity criteria for the test were satisfied. The 72 h E_rL50 and NOE_rL were determined to be > 100 mg/L (WAF) and ≥ 100 mg/L (WAF), respectively, based on the nominal loading concentration.

CONCLUSION Under the study conditions, the notified polymer is not considered to be harmful to algae up to the limit of its water solubility.

TEST FACILITY CERI (2013a)

C.2.4. Algal growth inhibition test

TEST SUBSTANCE Analogue

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species	*Selenastrum capricornutum* (green alga)
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L Actual: < 0.504 mg/L (limit of detection)
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Not reported
Remarks - Method	No significant deviation in protocol

RESULTS

Biomass		*Growth*	
E_bL50 *mg/L at 72 h*	*NOE_bL* *mg/L*	*E_rL50* *mg/L at 72 h*	*NOE_rL* *mg/L*
> 100	100	> 100	≥ 100

Remarks - Results

All validity criteria for the test were satisfied. The 72 h E_rL50 and NOE_rL were determined to be > 100 mg/L (WAF) and ≥ 100 mg/L (WAF), respectively, based on the nominal loading concentration.

CONCLUSION

Under the study conditions, the notified polymer is not considered to be harmful to algae up to the limit of its water solubility.

TEST FACILITY

Brixham (2005b)

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