File No: LTD/1978

June 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in 162046

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

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1978	Cintox Australia Pty Ltd	Polymer in 162046	ND*	≤ 1,000 tonnes per annum	Component of engine oils

*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.

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 reported use pattern and the low expected aquatic exposure, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified polymer during reformulation:
  - Avoid skin and eye contact

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

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

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 1,000;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of engine oils, or is likely to change significantly;
- the amount of polymer being introduced has increased, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Cintox Australia Pty Ltd (ABN: 63 122 874 613)
Suite 1, Level 2, 38-40 George Street
PARRAMATTA NSW 2150

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, use details, additive/adjuvants and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: boiling point, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, flammability, explosive properties and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME
162046 (product containing the notified polymer at < 60% concentration)

MOLECULAR WEIGHT
> 1,000 Da

ANALYTICAL DATA
Reference FTIR and GPC were provided.

3. COMPOSITION

DEGREE OF PURITY
> 80%

4. PHYSICAL AND CHEMICAL PROPERTIES

Note: the following measured physico-chemical properties are for a product containing the notified polymer at < 60% concentration in organic solvent

APPEARANCE AT 20 °C AND 101.3 kPa: Liquid

Property	Value	Data Source/Justification
Pour Point	-29 °C	Measured
Boiling Point	Not determined	Expected to decompose prior to boiling
Density	1062.8 kg/m^3 at 20 °C	Measured
Vapour Pressure	2.6 ×10^{-7} kPa at 20 °C	Measured
Water Solubility	8.7 × 10^{-5} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities; however, not expected to significantly hydrolyse under environmental conditions (pH 4-9)

Property	Value	Data Source/Justification
Partition Coefficient (n-octanol/water)	log Pow = 17.87	Measured
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on surface activity
Dissociation Constant	Not determined	The notified polymer is a salt and expected to be ionised under environmental conditions
Flash Point	200 °C (pressure unknown)	Measured
Flammability	Not determined	-
Autoignition Temperature	384 °C	Measured
Explosive Properties	Predicted negative	Estimated
Oxidising Properties	Predicted negative	Estimated

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.

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 in Australia. It will be imported as a component of lubricant additive packages at ≤ 30% concentration for reformulation, or as a component of finished engine oils at ≤ 12% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 1,000	≤ 1,000	≤ 1,000	≤ 1,000	≤ 1,000

PORT OF ENTRY
Typically Sydney, Melbourne, Perth and Brisbane

TRANSPORTATION AND PACKAGING
The additive packages containing the notified polymer at ≤ 30% concentration will be imported by ship, contained in either 20,000 L isotanks or in 205 L steel drums. The isotanks will be offloaded to tank trucks or rail cars at the port for distribution to lubricant manufacturing customers, while the 205 L steel drums will be shipped directly. The finished oils containing the notified polymer at ≤ 12% concentration will be packaged in 205 L drums or 1-4 L plastic bottles for distribution to service stations and end-use customers.

USE
The notified polymer will be used as a component of automotive engine oils at ≤ 12% concentration.

OPERATION DESCRIPTION

Reformulation
At the reformulation sites, the additive package containing the notified polymer at ≤ 30% concentration will be transferred from isotanks on rail cars and tank trucks into storage tanks through 10 cm hosing and pumping equipment. From the storage tanks, the additive package containing the notified polymer will be transferred to blending tanks through a computer controlled automated valve process and fixed lines. The product will be blended using a typical liquid blending process in a closed system with other components into finished oil products containing ≤ 12% of the notified polymer. The finished oil will be transferred back to the storage tanks where it will be filled into 205 L drums or 1-4 L plastic bottles.

End-use
Automotive manufacturers
At the automotive manufacturing sites, the finished oil product (containing the notified polymer at ≤ 12% concentration) will be pumped using hoses from the drums into the vehicle oil reservoir as the vehicle passes along a continuous production line.

Motor mechanics
Motor mechanics may pump or manually transfer the finished oil product (containing the notified polymer at ≤ 12% concentration) from the 205 L drums or 1-4 L bottles to the vehicle oil reservoir. The motor mechanic will also manually drain spent lubricant containing the notified polymer from the engine during servicing.

Do-It-Yourself (DIY) users
DIY users will manually transfer the product (containing the notified polymer at ≤ 12% concentration) from the 1-4 L bottles into the vehicle oil reservoir. They will also manually drain spent lubricant containing the notified polymer from the engine during servicing.

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 workers	2	30
Unloading isotanks and drums of additive package	0.5	30
Sampling and analysing additive package	0.1	220
Unloading isotanks and drums of finished oil	0.5	30
Sampling and analysing finished oil	0.1	220
Loading oil into tank trucks	0.5	220
Distribution to service stations	0.5	220
Automotive manufacturers	8	220
Automotive mechanics	1	200

EXPOSURE DETAILS
Transport and Storage
Transport and storage workers may come into contact with the notified polymer at ≤ 30% concentration only in the event of accidental rupture of containers.

Reformulation
The blending process is expected to be automated in a closed system; however, plant operators may be exposed (dermal and ocular) to the notified polymer at ≤ 30% concentration during opening of containers and connection/disconnection of transfer lines. Workers may also come into contact with the notified polymer during maintenance, cleaning, and sampling.

Dermal and ocular exposure to workers should be mitigated through engineering controls such as the use of a special air back flush system to prevent spillage during transfer and the use of notifier anticipated personal protective equipment (PPE) including coveralls, safety glasses and gloves. Inhalation exposure is not expected given the low vapour pressure of the notified polymer.

End-use
At car manufacturing sites, the finished engine oil containing the notified polymer ≤ 12% concentration will likely be added to engines using automated systems and exposure is unlikely. However, dermal and ocular exposure from drips, spills and splashes as well as from handling equipment contaminated with engine oil is possible. The potential for dermal and ocular exposure is expected to be reduced by the wearing of PPE (e.g. coveralls, safety glasses and gloves).

At automotive service centres, professional users such as mechanics may experience dermal or ocular exposure to the engine oil products containing the notified polymer at ≤ 12% concentration when topping up or changing engine oil. The potential for dermal and ocular exposure may be mitigated through the use of PPE (e.g. coveralls, safety glasses and gloves).

Overall, workers exposure to the notified polymer at ≤ 12% concentration in finished engine oils is not expected to be significant.

6.1.2. Public Exposure

Dermal and ocular exposure to the notified polymer at ≤ 12% concentration may occur to DIY users when topping up or changing engine oils. Given engine oil is topped up or changed infrequently and the low concentration of the notified polymer in the finished products, public exposure to the notified polymer is expected to be low.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on a product containing the notified polymer at ~53% concentration in organic solvent 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
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity combined with reproductive/developmental toxicity screening	NOAEL = 1000 mg/kg bw/day for repeated dose and reproductive/developmental toxicity
Mutagenicity – bacterial reverse mutation*	non mutagenic
Genotoxicity – in vitro chromosomal aberration*	non genotoxic

*Test concentrations adjusted for the concentration of the notified polymer in the test substance

Toxicokinetics

Absorption of the notified polymer across biological membranes (gastrointestinal tract and skin) is expected to be limited based on the high molecular weight (> 1,000 Da). However, the notified polymer contains a high proportion of low molecular weight species (< 1,000 Da) which may be absorbed.

Acute toxicity

A product containing the notified polymer at ~53% concentration was found to have low acute oral and dermal toxicity in studies conducted in rats. No acute inhalation toxicity studies were provided.

Irritation and sensitisation

A product containing the notified polymer at ~53% concentration was found to be slightly irritating to the skin and eyes in studies conducted in rabbits. However, given the notified polymer is only present in the product at ~53% concentration there is uncertainty if the skin and eye irritations effects observed are due to the notified polymer (solely or in part) or not.

In the skin irritation study, very slight to slight erythema was noted in all three test animals which persisted up to the 7 day observation. Desquamation was observed in two animals on day 7. All signs of irritation were resolved at the 14 day observation period.

In the eye irritation study, slight reddening of the conjunctivae was observed in all three test animals which persisted to the end of the study period (21 days) in one animal.

A Buehler test on a product containing the notified polymer at ~53% concentration in guinea pigs did not reveal evidence of reactions indicative of skin sensitisation.

Repeated dose toxicity

In a combined repeated dose and reproductive/developmental toxicity study in rats with a product containing the notified polymer at ~53% concentration, no adverse effects on parental animals were noted at doses up to 1,000

mg/kg bw/day. The No Observed Adverse Effect Level (NOAEL) for repeated dose toxicity was therefore established as 1,000 mg/kg bw/day in this study.

Mutagenicity/Genotoxicity
A product containing the notified polymer at ~53% concentration tested negative in a bacterial reverse mutation assay and in an *in vitro* chromosomal aberration test in human lymphocytes.

Toxicity for reproduction
In a combined repeated dose and reproductive/developmental toxicity study in rats with a product containing the notified polymer at ~53% concentration, no adverse reproductive or developmental outcomes were noted at doses up to 1,000 mg/kg bw/day. The NOAEL for reproductive and developmental toxicity was therefore established as 1,000 mg/kg bw/day in this study.

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.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the studies provided, the notified polymer at ~53% concentration is expected to be of low hazard, presenting only as a possible slight skin and eye irritant.

During reformulation workers may be exposed to the notified polymer at ≤ 30% concentration. At these concentrations, the potential risk of irritating effects is expected to be low. Furthermore, the risk is expected to be further minimised by the expected use of PPE including coveralls, imperious gloves and goggles, and largely automated and enclosed processes limiting exposure.

During end-use workers may be exposed to the notified polymer at ≤ 12% concentration when changing or topping-up engine oil. At these low end-use concentrations, the potential risk of significant irritating effects is not expected.

Overall, given the low hazard of the notified polymer and low end-use concentration, the risk to the health of workers is not considered unreasonable.

6.3.2. Public Health
DIY users may have dermal and ocular exposure to the notified polymer while changing automotive engine oils containing the notified polymer at ≤ 12% concentration. Given the low concentration of the notified polymer in finished products, expected low hazard, relatively infrequent use, the risk to the public from use of products containing the notified polymer is not considered unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will be imported into Australia as a component of lubricating oil additive or finished oil lubricant for original equipment manufacturer or for automotive engine oil. No significant release of the notified polymer is expected from transportation and storage except in the unlikely event of accidental spills or leaks.

Local blending and repackaging of the additive containing the notified polymer into finished oil products is expected to occur within enclosed automated systems. Blending tanks and equipment are expected to be cleaned with mineral oil, which is expected to be recycled during subsequent blending. Accidental spills and leaks during normal blending and packaging procedures will be contained and collected for recycling where appropriate, or disposed of in accordance with local government regulations, most likely to landfill.

RELEASE OF CHEMICAL FROM USE

The finished products containing the notified polymer will be used as a component of automotive engine oil. Release during use may arise from spills when pouring lubricants into automotive vehicles or from vehicle leaks, and is expected to be very low.

RELEASE OF CHEMICAL FROM DISPOSAL

After reformulation, empty import containers containing residues of the notified polymer are expected to be sent to a container recycling facility for reconditioning. Empty containers will be washed with mineral oil and the wastes containing the notified polymer collected for disposal in accordance with local government regulations. Therefore, the release of the notified polymer to surface waters from the cleaning of empty containers is expected to be limited.

The major release of the notified polymer to the environment is expected from inappropriate disposal of waste or used lubricants. Lubricant products containing the notified polymer will be poured into automotive vehicles at automotive service centres or by do-it-yourself (DIY) consumers. A survey by the Australian Institute of Petroleum (AIP, 1995) indicates that of the annual sales of engine oils in Australia, 60% of oils are potentially recoverable (i.e. not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases is disposed of responsibly (e.g. oil recycling). Assuming this is the case, negligible release of the notified polymer should result from these professional activities. The remaining 14% of oil is used by DIY consumers.

According to a survey tracing the fate of used lubricating oil in Australia (Snow, 1997), approximately 20% of oil used by DIY consumers is collected for recycling, approximately 25% is buried or disposed of to landfill, 5% is disposed of into stormwater drains, and the remaining 50% is used in treating fence posts, killing grass and weeds or disposed of in other ways. In a worst case scenario involving the 14% of oil used by DIY consumers, up to 0.7% (14% × 5% stormwater disposal) of the total import volume of the notified polymer (or 7,000 kg) may enter the aquatic environment via disposal to stormwater drains. Since the use of the engine oils will occur throughout Australia, all releases resulting from use or disposal of used oil will be very diffuse. Release of the notified polymer in neat concentrations is unlikely except as a result of transport accidents.

7.1.2. Environmental Fate

Based on the results of a biodegradability study, the notified polymer is not expected to be readily biodegradable (10% in 28 days for a product containing the notified polymer at ~53% concentration). For details of the environmental fate study, please refer to Appendix C. The notified polymer, however, is not expected to be bioaccumulative based on its high molecular weight and surfactant properties.

The majority of the notified polymer will be thermally decomposed during use, or collected for recycling and re-refined. Up to 0.7% of annual import volume of the notified polymer (or 7,000 kg) may be released to stormwater drains from incorrect disposal of wastes and used engine oils by DIY consumers. In surface waters, the majority of the notified polymer is expected to partition to soil and sediment based on its surfactant properties. In landfill and in soil and sediment, the notified polymer is expected to eventually degrade by biotic and abiotic processes to form water and oxides of carbon, sulphur and calcium.

7.1.3. Predicted Environmental Concentration (PEC)

For the worst case scenario, the percentage of the imported quantity of notified polymer inappropriately disposed to stormwater drains is estimated to be 0.7%. That is, 14% (fraction collected by DIY users) × 5% (fraction disposed to stormwater). The release of the notified polymer may be up to 7,000 kg/year (= 1,000 tonnes/year × 0.7%). In this worst case scenario, it is assumed that the release goes into stormwater drains in a single metropolitan area with a geographical footprint of 500 km^2 and an average annual rainfall of 500 mm, all of which drains to stormwater. With a maximum annual release into this localised stormwater system of 7,000 kg and the annual volume of water drained from this region estimated to be 250 × 10^6 m^3, the calculated PEC will be up to 28 µg/L. This result reflects a worst-case scenario upper limit, as in reality releases of the notified polymer will be distributed over multiple regions and it will be further diluted if it reaches the ocean.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on a product containing the notified polymer at ~53% concentration in organic solvent 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 > 53 mg/L (WAF*)	Inconclusive
Daphnia Toxicity	48 h EL50 > 53 mg/L (WAF*)	Inconclusive
Algal Toxicity	72 h E_rL50 > 53 mg/L (WAF*)	Inconclusive

*Water accommodated fraction

As no specific endpoint was determined in the fish, daphnia and algal study, the toxic effects of the notified polymer to aquatic life is inconclusive. Therefore, the notified polymer is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009) 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 as 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 a PNEC is not available due to the low potential for release to the aquatic compartment based on its assessed use pattern in engine oils. Although the test substance containing the notified polymer is not readily biodegradable, it is not expected to bioaccumulate based on its high molecular weight and surfactant properties. On the basis of the maximum annual importation volume, low expected aquatic exposure and assessed use pattern in engine oils, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Note: the following measured physico-chemical properties were obtained on a product containing the notified polymer at ~53% concentration in organic solvent

Melting Point/Freezing Point -29 °C

Method	OECD TG 102 Melting Point/Melting Range.
Remarks	Determined using ASTM D5950.
Test Facility	Exempt Information (2016a)

Density 1062.8 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids.
Remarks	Determined using an oscillating densitometer.
Test Facility	Exempt Information (2016b)

Vapour Pressure 2.6×10^{-7} kPa at 20 °C

Method	OECD TG 104 Vapour Pressure.
Remarks	Determined using the Maxwell-Bonnell method.
Test Facility	Exempt Information (2016c)

Water Solubility 8.7×10^{-5} g/L at 20 °C

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method. The water solubility was based on the major components of the notified polymer.
Test Facility	Exempt Information (2015a)

Partition Coefficient (n-octanol/water) log Pow = 17.87

Method	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	HPLC Method. A weighted average Log Kow value of 17.87 has been calculated using various alkylphenol reference materials.
Test Facility	Exempt Information (2015b)

Flash Point 200 °C (pressure unknown)

Method	PMCU Test Code 10330-ASTM D 92
Remarks	Determined using Cleveland Open Cup tester
Test Facility	Exempt Information (2016b)

Autoignition Temperature 384 °C

Method	In-house cool flame method.
Test Facility	Southwest Research Institute (2015)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Product containing the notified polymer at ~53% concentration
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Crl:CD (SD)
Vehicle	Nil
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 F	2000	0/3
2	3 F	2000	0/3

LD50	> 2000 mg/kg bw
Signs of Toxicity	There were no deaths or test substance related clinical signs.
Effects in Organs	Small thyroid gland and clear fluid contents in the uterus were observed in one animal.
Remarks - Results	The animals showed expected body weight gain over the observation period.
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	WIL Research (2016a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Product containing the notified polymer at ~53% concentration
METHOD	OECD TG 402 Acute Dermal Toxicity.
Species/Strain	Rat/Crl:CD (SD)
Vehicle	Nil
Type of dressing	Semi-occlusive
Remarks - Method	No significant protocol deviations

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Two males and two females showed very slight erythema (grade 1) on day 1. One male showed brownish discolouration of skin within the test substance application site on day 1. Desquamation was observed on one female on day 3. These observations were completely subsided on day 4.
Signs of Toxicity - Systemic	No signs of systemic toxicity were observed.
Effects in Organs	No abnormal macroscopic findings were noted at necroscopy.
Remarks - Results	The body weight of the animals was within the range commonly recorded for this strain and age.
CONCLUSION	The test substance is of low toxicity via the dermal route.
TEST FACILITY	WIL Research (2016b)

B.3. Irritation – skin

TEST SUBSTANCE	Product containing the notified polymer at ~53% concentration
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 M
Vehicle	Nil
Observation Period	14 days
Type of Dressing	Semi-occlusive
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			
Erythema/Eschar	1.3	1.6	1	2	< 14 days	0
Oedema	0	0	0	0	-	0

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

Remarks - Results	Very slight to slight erythema was noted in all 3 animals which persisted up to the 7 day observation. Desquamation was observed in two animals on day 7. All signs of irritation were resolved at the 14 day observation period. Changes in body weight gain were within the range expected for rabbits used in this type of study.
CONCLUSION	The test substance is slightly irritating to the skin.
TEST FACILITY	WIL Research (2016c)

B.4. Irritation – eye

TEST SUBSTANCE	Product containing the notified polymer at ~53% concentration
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 M
Observation Period	21 days
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	0.3	0.3	0.3	2 (1 h)	More than 21 days	1
Conjunctiva: chemosis	0	0	0	0	-	0
Conjunctiva: discharge	0	0	0	0	-	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	Moderate reddening (grade 2) of the conjunctivae was noted in all animals at the 1-hour observation. Slight reddening (grade 1) was observed in all animals at the 24-hour observation and persisted up to the 72-hour observation in one animal, up to the 10-day observation in another animal

and up to the 21-day observation in another animal.

Brown discharge in the treated eyes was observed in all animals at the 1-hour observation and clear discharge in the treated eyes in two animals was observed at the 1-hour observation.

There was no unscheduled mortality or clinical signs of systemic toxicity.

CONCLUSION The test substance is slightly irritating to the eye.

TEST FACILITY WIL Research (2016d)

B.5. Skin sensitisation

TEST SUBSTANCE Product containing the notified polymer at ~53% concentration

METHOD OECD TG 406 Skin Sensitisation – Modified Buehler Method

Species/Strain Guinea pig/Crl:HA

PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: 100%

MAIN STUDY

Number of Animals Test Group: 10/sex Control Group: 5/sex

Vehicle Nil, for the test group and 70%/30% acetone/polyethylene glycol 400 for positive control group

Positive control Conducted parallel with the test substance using α-hexylcinnamaldehyde.

INDUCTION PHASE Induction Concentration:
topical: 100%

Signs of Irritation Moderate patchy erythema (grade 1) was observed in the induction phase in 10/20 of the test group animals. In the positive control group, moderate to severe erythema was observed in 9/10 animals.

CHALLENGE PHASE

1st challenge topical: 100%

2nd challenge Not performed

Remarks - Method A rechallenge was not performed on the test group due to the nil sensitisation response from the first challenge phase. The positive control group showed 10% incidence index at the first challenge phase below the requirement for a non-adjuvant positive control of at least 15%. Therefore a rechallenge was performed 7 days after the first challenge on the positive control group. An incidence index of 20% was noted following rechallenge supporting the sensitivity and reliability of the experimental technique.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100%	0/20	0/20	-	-
Control Group	100%	0/10	0/10	-	-
Positive Control	20%	1/10	0/10	2/10	0/10
	10%	0/10	0/10	0/10	0/10

Remarks - Results Dermal scores of ≥ 1 were not observed in the test and control animals at challenge.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.

TEST FACILITY WIL Research (2016e)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Product containing the notified polymer at ~53% concentration
METHOD	OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test.
Species/Strain	Rats/Crl:CD(SD)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 32 days for males; until Day 4 of lactation for females (39-44 days) Dose regimen: 7 days per week Post-exposure observation period: 15 days
Vehicle	Corn oil
Remarks - Method	The study evaluated systemic toxicity, including mortality, clinical chemistry and effects in organs and reproductive toxicity, including gonadal function, mating behaviour, conception, parturition and early postnatal development, of the test substance. No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	10/sex	0	0/20
low dose	10/sex	100	0/20
mid dose	10/sex	300	0/20
high dose	10/sex	1000	1/20
control recovery	5/sex	0	0/10
high dose recovery	5/sex	1000	0/10

Mortality and Time to Death

One female in high dose group died on day 53 (immediately after blood collection on the day of the recovery period necropsy). The study author asserted that there were no remarkable clinical observations prior to death and based on the timing of death in relation to blood collection, this death was considered to be accidental.

Clinical Observations

Test substance related increased incidences of red and/or clear material around the mouth and nose were noted approximately 1 hour following dose administration throughout the dosing period for animals in the high dose group. The study author asserted that although these observations were dose responsive, they were sporadic and persisted occasionally. Therefore these observations were considered non-adverse.

The hair loss and/or scabbing observed in both control and treated animals (both sexes) was considered incidental.

A statistically significant decrease in body weight gain was noted in the low dose group in males and low and mid dose groups in females during study days 7-13; while an increase in body weight gain was noted in the high dose group during study days 39-45 (recovery period) and during study days 35-38 in males and females, respectively. The study authors asserted that these differences were not dose-related and/or did not affect the absolute mean body weights and therefore were not considered to be test substance related.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Serum chemistry

During study week 4, males in the low dose group showed a statistically significant lower creatinine value and males in the low and high dose groups showed lower calcium and phosphorus values. During study week 6, males in the recovery high dose group showed a statistically significant reduction in mean calcium and statistically significant increase in mean potassium value. During study week 7, females in the high dose group showed a statistically significant increase in mean creatinine value.

Haematology

Reticulocyte values in males were significantly increased in the high dose group during study week 6 (recovery

necropsy) and this change was not observed in females. Males in the low and mid-dose groups showed a statistically significant decrease in platelet count and lower mean platelet volume, respectively, during study week 4.

Effects in Organs
Males in all dose groups showed statistically significant higher absolute and/or relative left epididymis weights. Statistically significant higher mean heart weight relative to final body weight was observed for males treated with mid dose of the test substance at the primary necroscopy.

Remarks – Results
No test substance related effects, on the number of F1 pups born, litter size, percentage of males at birth, F1 clinical observations, and postnatal survival and growth, were observed.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established as 1,000 mg/kg bw/day for repeated dose and reproductive/developmental toxicity in this study, based on the absence of test substance related toxicological significant effects at any of the doses administered.

TEST FACILITY WIL Research (2016f)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Product containing the notified polymer at ~53% concentration

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation method

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98 and TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthaflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: up to 5000 µg/plate b) Without metabolic activation: up to 5000 µg/plate
Vehicle	Tetrahydrofuran
Remarks - Method	Concentrations for main test were chosen based on the preliminary test conducted on TA100, TA1535 and WP2*uvr*A (base-pair substitution type) and on TA98 and TA1537 (frameshift type) results. No significant protocol deviations.

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	-	-	negative
Test 2	-	> 5000	≥ 500	negative
Present				
Test 1	> 5000	-	-	negative
Test 2	-	> 5000	≥ 500	negative

Remarks – Results Small, statistically significant increases in the frequency of revertant colonies were observed in the preliminary test (Test 1) at 150 µg/plate (TA1537) and in the main test (Test 2) at 15 µg/plate (TA1535) in the presence of S9 mix. There was no corresponding significant increase in the revertant colonies at any other doses. According to the study authors, these increases were considered of no biological relevance because there was no evidence of a dose-response relationship or reproducibility. Moreover, the individual revertant counts were either within or at the maximum limit of the historical untreated and vehicle control range for each strain.

A test item precipitate observed at ≥ 500 µg/plate became globular like at

≥ 1500 µg/plate. The study authors asserted that these observations did not prevent the scoring of revertant colonies.

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 test substance was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Envigo (2015)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE Product containing the notified polymer at ~53% concentration

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Species/Strain	*Human*
Cell Type/Cell Line	Human peripheral lymphocytes
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthaflavone induced rat liver
Vehicle	Tetrahydrofuran
Remarks – Method	A range finding study was conducted with and without metabolic activation at concentration range of 2.44-625 µg/mL.

The negative control was the vehicle tetrahydrofuran and the positive controls were mitomycin C (for -S9) and cyclophosphamide (for +S9).

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 2.5, 5.0*, 10.0*, 15.0*, 20.0*, 30.0 , MMC 0.2*	4 h	24 h
Test 2	0*, 2.5, 5.0*, 10.0*, 15.0*, 20.0*, 30.0, CP 1*	24 h	24 h
Present			
Test 3	0*, 2.5, 5.0*, 10.0*, 15.0*, 20.0*, 30.0, MMC 0.1*	4 h	24 h

*Cultures selected for metaphase analysis.
MMC - Mitomycin C
CP - Cyclophosphamide

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 625	> 30.0	≥ 20.0	negative
Test 2	> 625	> 30.0	≥ 15.0	negative
Present				
Test 3	> 625	> 30.0	≥ 20.0	negative

Remarks - Results The selection of the maximum dose level for the main test was based on the lowest precipitating dose level in the preliminary toxicity test.

The test item did not result in a statistically significant and/or dose dependent increase in the frequency of cells with chromosome aberrations compared to the vehicle control group both with and without S9.

The positive controls resulted in statistically significant increases in the incidence of chromosome aberrations with statistical significance under identical conditions.

CONCLUSION	The test substance was not clastogenic to human peripheral lymphocytes treated *in vitro* under the conditions of the test.
TEST FACILITY	Envigo (2016a)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

Test Substance	Product containing the notified polymer at ~53% concentration
Method	OECD TG 301 B Ready Biodegradability: CO2 Evolution Test.
Inoculum	Activated sewage sludge
Exposure Period	28 days
Auxiliary Solvent	Chloroform
Analytical Monitoring	Inorganic carbon (IC) analysis
Remarks - Method	No analysis was carried out to determine the homogeneity, concentration or stability of the test item formulation. This exception is considered not to affect the integrity of the study. Aside from this, the test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported. In view of the difficulties associated with the evaluation of the biodegradability of organic compounds with low water solubility, a modification to the standard method of preparation of the test concentration was performed. An approach endorsed by the International Standards Organisation (ISO, 1995) is to dissolve the test item in an auxiliary solvent prior to adsorption onto filter paper. High shear mixing was also applied to break up the filter paper containing the test item. Using this method the test item is evenly distributed throughout the test medium and the surface area of test item exposed to the test organisms is increased thereby increasing the potential for biodegradation.

Results

Test substance		*Toxicity control*		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*	*Day*	*% Degradation*
6	0	6	36	6	67
10	0	10	55	10	75
14	6	14	45	14	81
21	12	21	55	21	78
28	12	28	57	28	79

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound (sodium benzoate) surpassed the threshold level of 60% after 14 days (81%), and attained 76% degradation after 28 days. Therefore, the test indicates the suitability of the inoculums. The slight decrease in biodegradation between days 14 and 28 was considered to be due to sampling/analytical variation. The percentage degradation of the toxicity control surpassed the threshold level of 25% after 14 days (45%; 56% after 28 days), showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance after 28 days was 10%. Therefore, the test substance is not considered to be readily biodegradable according to the OECD (301 B) guideline.
Conclusion	The test substance is not readily biodegradable.
Test Facility	Envigo (2016b)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

Test Substance	Product containing the notified polymer at ~53% concentration
Method	OECD TG 203 Fish, Acute Toxicity Test – Semi-static.
Species	*Oncorhynchus mykiss* (rainbow trout)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	140 mg $CaCO_3$/L
Analytical Monitoring	HPLC-MS
Remarks – Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported. The test substance was prepared as water accommodated fraction (WAF) due to its low water solubility and complex nature of the test item. A nominal amount of test item (2,200 mg) was added to the surface of 22 litres of test water, stirred for 23 hours and allowed to stand for 1 hour, to give the 100 mg/L loading rate.

Results

Concentration mg/L		*Number of Fish*	*Cumulative Mortality*				
Nominal	*Actual*		*3 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	Control	7	0	0	0	0	0
100	0.294	7	0	0	0	0	0

LL50	> 53 mg/L (WAF) at 96 hours.
NOEL	53 mg/L (WAF) at 96 hours.
Remarks – Results	All validity criteria for the test were satisfied. The test solutions were renewed daily during the 96 h test period. The actual concentrations of the test substance were measured at 0, 24, 72 and 96 h hours. In the test report, the 96 h LL50 and NOEL for fish were determined to be > 100 mg/L and 100 mg/L (WAF), respectively, based on nominal loading concentrations. As the test substance contains 53% of the notified chemical, the 96 h LL50 and NOEL were recalculated to > 53 mg/L and 53 mg/L respectively, to predict the toxic effects caused by the notified polymer.
Conclusion	As a specific toxicity endpoint was not determined in this study, the toxicity of this notified polymer to fish is inconclusive.
Test Facility	Envigo (2016c)

C.2.2. Acute toxicity to aquatic invertebrates

Test Substance	Product containing the notified polymer at ~53% concentration
Method	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC-MS
Remarks - Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

The test substance was prepared as water accommodated fraction (WAF) due to its low water solubility and complex nature of the test item. A nominal amount of test item (200 mg) was added to the surface of 2 litres of test water, stirred for 23 hours and allowed to stand for 1 hour, to give the 100 mg/L loading rate.

Results

Concentration mg/L		*Number of D. magna*	*Cumulative Immobilised (%)*	
Nominal	*Actual*		*24 h*	*48 h*
Control	Control	20	0	0
100	<0.0011	20	0	0

EL50	> 53 mg/L (WAF) at 48 hours
NOEL	53 mg/L (WAF) at 48 hours
Remarks - Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 48 h test period. The actual concentrations of the test substance were not measured as no effects were observed at the highest concentration tested. In the test report, the 48 h EL50 and NOEL for daphnids were determined to be > 100 mg/L and 100 mg/L (WAF), respectively, based on nominal loading concentrations. As the test substance contains 53% of the notified polymer, the 48 h EL50 and NOEL were recalculated to 53 mg/L and 53 mg/L respectively, to reflect the toxic effects caused by the notified polymer.
Conclusion	As a specific toxicity endpoint was not determined in this study, the toxicity of this notified polymer to invertebrates is inconclusive.
Test Facility	Envigo (2016d)

C.2.3. Algal growth inhibition test

Test Substance	Product containing the notified polymer at ~53% concentration
Method	OECD TG 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test.
Species	*Pseudokirchneriella subcapitata* (green alga)
Exposure Period	72 hours
Concentration Range	Nominal: 10-100 mg/L Actual: < 0.00044 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	HPLC-MS
Remarks - Method	The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported. The test substance was prepared as water accommodated fraction (WAF) due to its low water solubility and complex nature of the test item. A nominal amount of test item (200 mg) was added to the surface of 2 litres of test water, stirred for 23 hours and allowed to stand for 1 hour, to give the 100 mg/L loading rate.

Results

Biomass		*Growth*	
E_yL50	*NOEL*	*E_rL50*	*NOEL*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
> 53	53	> 53	53

Remarks - Results	All validity criteria for the test were satisfied. The actual concentrations of the test substance were measured at the start and end of the 72 h test period. In the test report, the 72 h EL50 and NOEL was determined to be > 100 mg/L and 100 mg/L (WAF), respectively, based on nominal concentration. As the test substance contains 53% of the notified polymer, the 72 h EL50 and NOEL were recalculated to > 53 mg/L and 53 mg/L respectively, to predict the toxic effects caused by the notified polymer.
Conclusion	As a specific toxicity endpoint was not determined in this study, the toxicity of this notified chemical to algae is inconclusive.
Test Facility	Envigo (2016e)

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