File No: STD/1621

November 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Ethene, homopolymer, distn. residues

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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1621	Chevron Phillips Chemicals Australia Pty Ltd	Ethene, homopolymer, distn. residues	No	≤ 100 tonnes per annum	Coating for fertilisers.

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself. However, these should be selected on the basis of all ingredients in the formulation.

  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.

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

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

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

ASSESSMENT DETAILS

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

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Chevron Phillips Chemicals Australia Pty Ltd (ABN: 29 107 015 896)
Suite 409, 685 Burke Road
CAMBERWELL VIC 3124

NOTIFICATION CATEGORY
Standard (Reduced fee notification): Synthetic polymer with Mn < 1,000 Da (more than 1 tonne per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: structural formulae, molecular weight, analytical data and use details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: water solubility, acute oral toxicity, acute dermal toxicity, skin irritation, eye irritation, skin sensitisation, repeated dose toxicity, genotoxic damage *in vivo* and chromosome damage *in vitro*.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US EPA (2000) and Canada (2000)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
AlphaPlus® C30+ HA

CAS NUMBER
260255-62-7

CHEMICAL NAME
Ethene, homopolymer, distn. residues
(This is defined as the complex residuum from the polymerization of ethylene in the presence of an aluminium catalyst. It consists predominately of C26 to > C80 α-olefins and boils in the range of 236 °C to 557 °C (457 °F to 1035 °F).

OTHER NAME(S)
C30+ NAO

MOLECULAR FORMULA
Unspecified

MOLECULAR WEIGHT (MW)
Number average molecular weight (NAMW) is < 1000 g/mol

3. COMPOSITION

DEGREE OF PURITY
100 % (UVCB)

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White, waxy solid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	> 100 °C	Estimated
Boiling Point	> 380 °C at 101.3 kPa	Estimated
Density	840 kg/m^3 at 15.6 °C	Measured/ASTM D1298
Vapour Pressure	< 1 × 10^{-10} psi at 100 °C	Measured/ASTM D2878-95
Water Solubility	1.75 × 10^{-8} mg/L at 25 °C	Measured by Safepharm Laboratories for analogue 3.
Hydrolysis as a Function of pH	Not determined	Does not contain readily hydrolysable functionality.
Partition Coefficient (n-octanol/water)	log P_{ow} > 8	Estimated from HEDSET database for analogue 3.
Adsorption/Desorption	log K_{oc} = 8-12	Estimated by KOCWIN v2.00 for analogue 1-octacosene.
Dissociation Constant	Not determined	Does not contain dissociable functionality.
Particle Size	Not determined	The notified polymer is a waxy solid which is not expected to form respirable particles.
Flash Point	250 °C at 101.3 kPa	Measured/ Pensky-Martens closed cup
Flammability	Will burn in the presence of enough heat and air	Estimated
Autoignition Temperature	391 °C	SDS
Explosive properties	Not determined	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties.

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System 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 into Australia by sea as a component of finished products. The finished products may be imported as unblended (containing only the coated component) or blended (containing the coated component and other solid fertilising components such as micronutrients). Both the unblended and blended products may be further reformulated for production of final soil fertilisers.

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

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

PORT OF ENTRY

The products containing the notified polymer will be imported into Australia through the ports of Brisbane, Sydney, Melbourne and Fremantle.

IDENTITY OF MANUFACTURER/RECIPIENTS

Chevron Phillips Chemicals Australia Pty Ltd, Camberwell, VIC 3124

TRANSPORTATION AND PACKAGING
The products containing the notified polymer will be imported into Australia in small packages (25 kg bags) for distribution directly to the customers, or imported in bulk and then repackaged into smaller packages, or the material may be imported in bulk packages, blended with other solid fertiliser components and then repackaged and distributed to customers.

USE
The notified polymer is used as a coating for granular fertilisers. It will constitute up to 5% by weight of the finished product.

OPERATION DESCRIPTION
The imported finished products already coated with the notified polymer may be further blended with other solid components. The blended products are finally packaged in bulk bags or shrink-wrapped pallets of 25 kg bags for storage at the fertiliser retailers and distributers.

The fertilisers coated with the notified polymer will be applied to soil by workers and the public.

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	4	8
Loading/Blending	2	30
Equipment cleaning	2	30
Fertiliser loading into application equipment	5	15

EXPOSURE DETAILS

Transport and Storage
Transport and storage workers are unlikely to be exposed to the notified polymer. Dermal exposure may occur only in the case of accidental breach of the product packaging during unloading and transport to the customer sites.

Blending and Packaging
Workers may have dermal, ocular and potentially inhalation exposure to the notified polymer during following activities:

- Loading of blending equipment
- Packaging of the blended product containing the notified polymer into bulk bags or shrink-wrapped pallet 25 kg bags
- Loading of formulated product from storage bags into agricultural applicators for spreading the product onto landscapes at various public sites and facilities
- Manual application of the fertiliser onto soil

It is expected that workers with potential for exposure to the finished fertiliser product will wear appropriate personal protective equipment (PPE) to avoid dermal exposure and inhalation and contact with eyes from any incidental dust that may be created from further handling and mechanical processing. As the material is waxy, it is considered less likely to form dust.

6.1.2. Public Exposure
Slow release fertilisers are used by consumers and at work sites such as lawns, golf courses, nurseries, greenhouses and crops. Public parks are also a potential site of use. There is potential for direct dermal exposure of the general population to the notified polymer, based on the expected widespread use.

6.2. Human Health Effects

No toxicity data were submitted for the notified polymer. However, test results of the analogues C30+ Alkenes, branched and linear, alpha (Analogue 1), C24-30 Alkenes, branched and linear (Analogue 2) and C20-24 Alkenes, branched and linear (Analogue 3) were provided as read-across for the human health endpoints. These analogues were accepted because of their high structural similarity to the notified polymer. Other analogues were also considered in the Canada assessment.

The results from toxicological investigations submitted on analogues of the notified polymer are summarised in the following table. For full details of the studies not previously assessed by Canada, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity[1]	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity[3]	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation[3]	non-irritating
Rabbit, eye irritation[3]	non-irritating
Guinea pig, skin sensitisation – adjuvant test[3]	no evidence of sensitisation
Rat, repeat dose oral toxicity – 90 days[3]	NOAEL = 1000 mg/kg/day
Mutagenicity – bacterial reverse mutation[2, 3]	non mutagenic
Genotoxicity – *in vitro* chromosomal aberration assay[3]	non genotoxic
Genotoxicity – *in vivo* mouse micronucleus assay[3]	non genotoxic

[1]Analogue 1
[2]Analogue 2
[3]Analogue 3

Toxicokinetics, metabolism and distribution

No toxicokinetic data were provided for the notified polymer. The notified polymer has a significant proportion of species with molecular weight < 1000 g/mol, but also very low water solubility (< 1.19×10^{-9} mg/L). This is expected to restrict transport across biological membranes.

Acute toxicity

No acute toxicity data were provided for the notified polymer. However, the notified polymer is not expected to cause acute oral toxicity based on the results of tests in rats with analogues 1 and 3 and also C22-28 alpha olefins. Acute dermal toxicity in rats was low for analogue 3, and also low when tested in rabbits with a blend containing C18-30 alpha olefins. Information on acute inhalation toxicity was not available, however inhalation exposure is not expected due to the estimated low vapour pressure of the notified polymer and its waxy nature that is unlikely to form dust particles.

Irritation and sensitisation

The notified polymer is not expected to be an eye irritant based on the results of acute eye irritation tests in rabbits with analogue 3 and C18-30 alpha olefins. Analogue 3 was not a skin irritant in rabbits.

A maximisation test in guinea pigs showed that analogue 3 did not cause allergic skin reactions. In addition, sensitisation tests in both guinea pigs (Buehler test) and humans (31 females and 5 males) indicated that another analogue, neodene 18 alpha olefin, did not cause sensitisation.

Repeated dose toxicity

Repeated oral exposures to the notified polymer are not expected to cause any significant organ toxicity based on the results of a 90-day oral toxicity test in rats with analogue 3, where the NOAEL was reported to be 1000 mg/kg/day.

In a 28-day reproductive, neurological (male only) and developmental toxicity study not reported in the table above, another analogue (1-tetradecene) had a NOAEL of 1000 mg/kg/day based on the absence of any observable adverse effects. A neurological NOAEL of 500 mg/kg/day was established for females based on a decrease in activity rates observed in the FOB test.

The notified polymer is not expected to cause neurotoxicity based on the results of the 90 day study on analogue 3, an acute toxicity test on another analogue (C16 alpha olefin), and other toxicity on alpha olefins in which no indicators of neurotoxic effects were observed.

Mutagenicity/Genotoxicity
The notified polymer is not expected to be genotoxic based on results of testing of analogues. Bacterial reverse mutation studies on analogues 2 and 3 were negative, as were an *in vitro* human lymphocyte chromosomal aberration assay and *in vivo* mouse micronucleus assay on analogue 3. These results are supported by the genotoxicity results obtained with other alpha olefins, including 1-octadecene, which was negative in a bacterial reverse mutation test, *in vitro* rat liver cell chromosome aberration assay and mitotic gene conversion assay using *Saccharomyces cerevisiae.*

Toxicity for reproduction
The notified polymer is not expected to cause any reproductive or developmental toxicity based on the results obtained from the 28-day oral reproductive and developmental toxicity study with 1-tetradecene. In this study the lowest NOAEL for maternal toxicity, reproductive toxicity and developmental toxicity were considered to be > 1000 mg/kg/day. In the 90-day oral toxicity study in rats with analogue 3, histopathology indicated no adverse effects on reproductive organs.

Health hazard classification
Based on the available analogue 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

Workers may experience dermal, ocular and potentially inhalation exposure to the notified polymer (used as a coating of fertiliser pellets) during reformulation, loading of agricultural applicators and manual application. However, the analogue data provided suggest that the notified polymer is not expected to have adverse local or systemic effects. The risk from inhalation exposure is also expected to be low because the notified polymer is a waxy solid that does not create dust. Therefore, the notified polymer is not expected to pose an unreasonable health risk to the workers.

6.3.2. Public Health
Given the expected widespread use of the notified polymer as a coating for soil fertilisers, there is potential for direct dermal exposure of the general population at low concentration and infrequent use. Inhalation exposure is not expected to occur. Based on the expected low hazard of the polymer indicated by the analogue data, the risk to the public associated with the use of the notified polymer as a fertiliser coating 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 coating on solid fertiliser products. The finished products may be imported as unblended (containing only coated material) or blended (where apart from the coated granular fertiliser, they contain other solid fertilising components such as micronutrients).

Both unblended and blended finished products already coated with the notified polymer may be further mixed with other solid components. The finished products are finally packaged in bulk bags or shrink-wrapped pallets of 25 kg bags for storage at the fertiliser retailers and distributers.

Liquid waste from cleaning of the reformulation equipment is expected to be disposed of in accordance with local government regulations. Accidental spills of the notified polymer during import, transport, reformulation, coating or storage are expected to be collected for recycling or disposal of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE
The notified polymer will be used as a coating for granular fertilisers. It will constitute up to 5% by weight of the finished product. The fertilisers coated with the notified polymer will be applied to soil in lawns, golf courses,

nurseries, greenhouses, public parks and crops using typical fertiliser application techniques. Empty product containers are expected to be disposed of to landfill in accordance with local government regulations. Notified polymer residues remaining in application equipment are expected to remain in situ, and are likely to be released to the soils during subsequent use of the equipment.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the introduction volume of the notified polymer is expected to be applied to agricultural soils. Any unused product containing the notified polymer is expected to be disposed of via an authorised waste disposal company in accordance with local regulations.

7.1.2. Environmental Fate

The fertilisers coated with the notified polymer will be applied to topsoil and expected to be effectively taken up by plants and crops. It may reach aquatic environments from run-off. However, in addition to good farming practices, efficient and economic use of the fertilisers is expected to minimise loss of the notified polymer to the aquatic environment. The notified polymer is expected to be immobile in soils based on its estimated negligible water solubility and very high log K_{oc}. Therefore, it is not expected to reach ground water. The notified polymer is not expected to be volatile due to its estimated low vapour pressure. If the notified polymer reaches the aquatic environment, it will initially float based on its expected negligible water solubility and estimated density < 1 kg/m^3. Any dissolved notified polymer will be strongly adsorbed to soil or sediment and immobile. The ready biodegradability tests conducted on structural analogues (93% degradation in 28 days for analogue 3 and 51% degradation in 28 days for analogue 2) indicate that the notified polymer would be inherently biodegradable in aerobic environment. For details of the biodegradability studies, please refer to Appendix C. The notified polymer is not expected to bioaccumulate due to its expected biodegradability. In waters, soils, and sediments, the residual notified polymer is expected to degrade via biotic and abiotic processes, to eventually form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The fertiliser containing the notified polymer is intended as part of a nutrient replacement program for agricultural land and actual application rates will depend on specific crop nutrient requirements. The Predicted Environmental Concentration (PEC) of the notified polymer in soil and water compartments is estimated below.

IN SOIL COMPARTMENT

It is assumed that the fertiliser containing the notified polymer will be applied at a rate of 100 kg/ha based on the rate of application of commercial fertilisers like Di-Ammonium Phosphate (DAP) (Impact fertilisers, 2017). As the notified polymer will constitute up to 5% by weight of the finished fertiliser, the worst case application rate for soil is about 5 kg notified polymer/ha.

IN WATER COMPARTMENT

The notified polymer may reach aquatic environments from run-off. The worst-case edge-of-field scenario may be considered assuming a 100 mm rainfall event with 20% of that water running off, resulting in 200 m^3 run-off water per hectare. The run-off water is assumed to carry 5% of the applied polymer (APVMA, 2016). This does not consider the uptake by crops, or degradation and mobility of the notified polymer. The worst case PEC_{runoff} from a run-off event right after an application is 1.25 mg/L [(5 kg/ha × 0.05) ÷ 200 m^3]. In reality, the notified polymer will strongly bind to soil based on its estimated limited water solubility and very high log $K_{oc.}$ Some notified polymer will be transported attached to eroded soil particles but most is expected to be bound to soil and degrade *in situ*, and therefore, the calculated PEC is a significant overestimation of the aquatic exposure.

7.2. Environmental Effects Assessment

The results from eco-toxicological investigations conducted on analogue 3 are summarised in the table below. Full details of the studies not previously assessed by Canada can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 > 1000 mg/L (WAF*)	Not harmful to fish up to its water solubility limit
Daphnia Toxicity	48 h LC50 > 1000 mg/L (WAF*)	Not harmful to aquatic invertebrates up to its water solubility limit
Algal Toxicity	72 h LC50 > 1000 mg/L (WAF*)	Not harmful to alga up to its water solubility limit
Earthworm Toxicity	28 d LC50 > 1000 mg/kg 28 d and 56 d NOEC = 500 mg/kg	Not harmful to earthworms

*WAF: Water Accommodated Fraction

Based on the above ecotoxicological endpoints for analogues of the notified polymer, it is not expected to be harmful to aquatic organisms up to its water solubility limit. Therefore, the notified polymer is not formally classified under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* for acute and chronic toxicities (United Nations, 2009). The notified polymer is also not harmful to earthworms (Mensink et al. 1995).

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) for environmental compartments has not been calculated as the notified polymer is not considered to be harmful to aquatic and terrestrial organisms.

7.3. Environmental Risk Assessment

The Risk Quotients (Q = PEC/PNEC) have not been calculated since the PNEC was not calculated. The notified polymer is not expected to be harmful to aquatic and terrestrial organisms. Therefore, based on the low toxicity to aquatic and terrestrial organisms, and the assessed use pattern as fertiliser coatings, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – dermal

TEST SUBSTANCE	Analogue 3
METHOD	OECD TG 402 Acute Dermal Toxicity
Species/Strain	Rat/Sprague-Dawley CD
Vehicle	None
Type of dressing	Semi-occlusive.
Remarks - Method	No deviations from the original protocol. The study was performed in compliance with GLP. A group of 10 animals was given a single, 24-hour semi-occluded, dermal application to intact skin at a dose level of 2000 mg/kg bodyweight. The animals were observed for evidence of dermal toxicity for 14 days after the day of treatment and were then sacrificed for gross pathological examination.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	10(5F/5M)	2000	None

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	There were no deaths. All animals showed expected gain in body weight during the study. No signs of skin irritation were noted during the study.
Signs of Toxicity - Systemic	No signs of systemic toxicity were noted during the study.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks - Results	The acute dermal median lethal dose (LD_{50}) of the test material in the rats was found to be greater than 2000 mg/kg bodyweight.
CONCLUSION	The test substance is of low acute toxicity via the dermal route.
TEST FACILITY	Safepharm (1998a)

B.2. Genotoxicity – bacteria

TEST SUBSTANCE	Analogue 2
METHOD	OECD TG 471 Bacterial Reverse Mutation Test EC Directive 2000/32/EC B.14 Mutagenicity – Reverse Mutation Test using Bacteria Plate incorporation procedure
Species/Strain	*Salmonella typhimurium*: TA1535, TA1537, TA98, TA100 *Echerichia coli*: WP2uvrA
Metabolic Activation System	S9 microsomal fraction from Aroclor 1254-induced rat liver
Concentration Range in Main Test	All *Salmonella* and E. coli strains With and without metabolic activation: 15-5000 µg/plate
Vehicle	Dimethyl sulphoxide (DMSO)
Remarks - Method	A preliminary toxicity test (0.15-5000 µg/plate) was performed to determine the toxicity of the test material in the presence and absence of metabolic activation in TA100 and WP2uvrA strains. Tests 1 and 2 were conducted on separate days using fresh cultures and test substance solutions. Test 1 was the range-finding study in which six concentrations of the test material (15-5000 µg/plate) were used in triplicates against each strain. The concentration range in Test 2 was based on the results of Test 1. Test 1 and 2: All strains with and without S9: 15, 50, 150, 500, 1500 and

5000 µg/plate

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 (TA100, WP2uvrA)	> 5000 for all strains	≥ 1500 for all strains	Negative
Test 2	-	> 5000 for all strains	≥ 1500 for all strains	Negative
Present				
Test 1	> 5000 (TA100, WP2uvrA)	> 5000 for all strains	≥ 1500 for all strains	Negative
Test 2	-	> 5000 for all strains	≥ 1500 for all strains	Negative

Remarks - Results

No toxicity was exhibited to any of the strains of bacteria used. An opaque film was observed at a dose of 1500 µg/plate and above, with oily droplets observed at 5000 µg/plate, however, this did not prevent the scoring of revertant colonies.

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

The positive and negative controls gave satisfactory results confirming the sensitivity of the test system.

CONCLUSION

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

TEST FACILITY

Safepharm (1998b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1.1. Ready biodegradability test 1

TEST SUBSTANCE	Analogue 3
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test EC Directive 84/449/EC C.6
Inoculum	Activated sludge from a local STP
Exposure Period	28 days
Auxiliary Solvent	Di-ethyl ether
Analytical Monitoring	Dissolved oxygen (DO) concentration using a Yellow Springs Biochemical Oxygen Demand (BOD) Meter
Remarks - Method	The test substance was dissolved in di-ethyl ether to give a stock solution of 112 mg/mL. 10 µL aliquots of stock solution were placed on individual pieces of Whatman GFA glass filter paper and the solvent was allowed to evaporate to dryness. One piece of paper was placed in each BOD bottle prior to filling with inoculated medium. Filter paper blanks were prepared in the same manner using solvent only. A toxicity control was run.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
5	18	5	69
15	53	15	81
28	93	28	81

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 % within 14 days indicating the suitability of the inoculums. The toxicity control exceeded 25% biodegradation after 14 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 93%, but the pass level of 60% was not achieved within 10 day window.
CONCLUSION	The test substance is not ready biodegradable, but inherently biodegradable.
TEST FACILITY	HRC (1993)

C.1.2. Ready biodegradability test 2

TEST SUBSTANCE	Analogue 2
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test EC Directive 92/69/EC C.4 US EPA Test Guidelines OPPTS 835.3110
Inoculum	Activated sludge from a local STP
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	CO_2 using an Ionics 1555B Total Organic Carbon (TOC) analyser, and Dissolved Organic Carbon (DOC) using a Shimadzu 5050A TOC Analyser
Remarks – Method	An amount of the test substance (35.1 g) was adsorbed onto the surface of 100 mg of granular silica gel prior to dispersal in approximately 100 mL of culture medium with aid of high shear mixing. The test dispersion was then dispersed in inoculated culture medium and the volume adjusted to 3 litres to give a final concentration of 10 mg C/L. The silica gel helped to

enhance dispersion of the test material in the test medium, and to increase the surface area of the test material exposed to the test organisms. Control and reference vessels were prepared containing 100 mg silica gel per 3 litres of inoculated culture medium in order to maintain consistency between these vessels and the test substance vessels. A toxicity control was run.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	27	7	65
14	35	14	71
21	38	21	75
28	51	28	85

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 % within 14 days indicating the suitability of the inoculums. The toxicity control exceeded 25% biodegradation after 14 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 51%.

CONCLUSION: The test substance is not ready biodegradable, but shows inherent biodegradability.

TEST FACILITY: Safepharm Laboratories Limited (2000)

C.2 Ecotoxicological Investigations

C.2.1. Acute toxicity in earthworm

TEST SUBSTANCE: Alkane 4 (an analogue of the notified polymer)

METHOD: OECD TG 222 Earthworm Reproduction Test

Species: *Eisenia foetida*

Exposure Period: 28 days (mortality), 56 days (reproduction)

Auxiliary Solvent: Acetone

Analytical Monitoring: None

Remarks - Method: An amount of test substance (312.5, 625, 1250, 2500, and 5000 mg) was separately dissolved in 500 mL acetone. An aliquot (4 × 90 mL) of each of the solvent stock solution was separately added to approximately 250 g of artificial soil and the acetone was allowed to evaporate off. After evaporation, the soil was incorporated into a further 3.6 kg of artificial soil and water using a Hobart A200N mixer to give the expected test concentrations with nominal moisture content of 30% of dry weight. Preliminary works conducted using various methods of addition of the test substance to artificial soil including the above procedure showed that it was not possible to recover nominal concentrations from bulk preparations. This was considered due to the test material binding strongly to the soil (with estimated log K_{oc} = 10, US EPA, 2012) and then not being extracted by the analytical procedure. Given that the solvent stock solutions were shown to have near nominal test substance concentrations, it was considered appropriate to base the results of the study on nominal concentrations only. The solvent control was prepared by adding an aliquot (14.4 mL) of acetone to approximately 100 g of artificial soil. After 28 days exposure, the adult earthworms were removed from the test vessels and the number of mortality was recorded. After 56 days, the number of juvenile earthworms present was recorded. Statistical analysis of the adult and juvenile earthworm data was performed using Barlett's

test and Dunnett's procedure. A toxicity control was run.

RESULTS

Concentration mg/L		*Initial number of Earthworms*	*Results*	
Nominal	*Actual*		*28 d Mortality (% of initial number of earthworms)*	*56 d Reproduction (% of reproduction in solvent control)*
Control	Control	40	8	147
Solvent control	Solvent control	40	5	100
62.5	Not determined	40	8	107
125	Not determined	40	18	76
250	Not determined	40	13	93
500	Not determined	40	18	90
1000	Not determined	40	18	9

LC50	>1000 mg/L at 28 d
EC50 (reproduction)	630 mg/L at 56 d (calculated by probit method)
NOEC (or LOEC)	500 mg/L at 28 d and 56 d
Remarks - Results	All validity criteria for the test were satisfied.

CONCLUSION The test substance is not harmful to earthworms

TEST FACILITY Harlan Laboratories Ltd (2010)

BIBLIOGRAPHY

Australian Pesticides and Veterinary Medicines Authority (APVMA) (2016).

Harlan Laboratories Ltd (2010) Alkane 4: Earthworm Reproduction Test (Project No. 1635/0061). Derbyshire, England (Unpublished report submitted by the notifier).

Huntingdon Research Centre (HRC) (1993) Gulftene 20-24 Ready Biodegradability - Closed Bottle Test (Report No. 46(b)/930353). Cambridgeshire, England (Unpublished report submitted by the notifier).

Impact fertilisers (2017) http://www.impactfertilisers.com.au/products/phosphorus/dap/.

Mensink BJWG, Montforts M, Wijkhuizen-Maslankiewicz L, Tibosch H and Linders JBHJ (1995) Manual for summarising and evaluating the environmental aspects of pesticides, Bilthoven, The Netherlands, National Institute of Public Health and Environmental Protection, Report No. 679101022, Appendix 5, <http://www.rivm.nl/bibliotheek/rapporten/679101022.html>.

Safepharm (1998a) C20-C24 Alkenes, branched and linear (C1829-50A): Acute dermal toxicity study in the rat (Study No. 703/117, April 1998). Derby, UK, Safepharm Laboratories Limited (Unpublished report submitted by the notifier)

Safepharm (1998b) C24-C30 Alkenes, branched and linear (ID# C1829-50B): *Salmonella typhimurium* and *Echerichia coli* reverse mutation assay (Study No. 703/087, May 1998). Derby, UK, Safepharm Laboratories Limited (Unpublished report submitted by the notifier)

Safepharm Laboratories Limited (1998c) C20-C24 Alkenes, Branched and Linear: Acute Toxicity to Rainbow Trout *Oncorhynchus mykiss* (Project No. 703/123). Derby, UK (Unpublished report submitted by the notifier).

Safepharm Laboratories Limited (1998d) C20-C24 Alkenes, Branched and Linear: Acute Toxicity to *Daphnia magna* (Project No. 703/124). Derby, UK (Unpublished report submitted by the notifier).

Safepharm Laboratories Limited (1998e) C20-C24 Alkenes, Branched and Linear: Algal Inhibition Test (Project No. 703/125). Derby, UK (Unpublished report submitted by the notifier).

Safepharm Laboratories Limited (2000) C24-30 Alkenes: Assessment of Ready Biodegradability CO_2 Evolution Test (Project No. 703/214). Derby, UK (Unpublished report submitted by the notifier).

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >