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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in OLI 9900

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

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1550	BP Australia Pty Ltd A S Harrison & Co Ltd	Polymer in OLI 9900	ND*	≤ 50 tonnes per annum	Fuel Additive

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

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 PEC/PNEC ratio 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

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced in diesel fuel additive packages:
  - Avoid skin and eye contact

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

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

Disposal

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

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by [method of treatment].

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 an additive in diesel fuels or is likely to change significantly;
- the amount of polymer being introduced has increased, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet
The (M)SDS's of products containing the notified polymer were provided by the notifier and 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)
BP Australia Pty Ltd (ABN: 53 004 085 616)
717 Bourke Street
Docklands VIC 3008

A S Harrison & Co Pty Ltd (ABN: 89 000 030 437)
75 Old Pittwater Road
Brookvale NSW 2100

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

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

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2004)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
OLI 9900 (product containing the notified polymer at ≤ 75% concentration)

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference GPC and FTIR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 85%

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< -20 °C	Estimated based on analogue data
Boiling Point	> 200 °C	Estimated based on analogue data
Density	976 kg/m^3 at 15 °C*	SDS
Vapour Pressure	Not determined	Expected to be low based on molecular weight and analogue data
Water Solubility	0.74-1.1 x 10^{-3} g/L at 20 °C	Estimated based on HPLC loading rate
Hydrolysis as a Function of pH	Not determined	Not expected at environmental pH; limited solubility in water

Partition Coefficient (n-octanol/water)	log Pow = 10.377	Calculated using KOWWIN v1.68 (US EPA, 2011)
Adsorption/Desorption	Not determined	Notified polymer is expected to strongly adsorb to soil
Dissociation Constant	Not determined	Notified polymer contains no dissociable functionalities
Flash Point	> 100 °C	Estimated based on analogue data
Flammability	Not expected to be flammable	Based on flash point and autoignition temperature
Autoignition Temperature	380 °C	Estimated based on analogue data
Explosive Properties	Not determined	Not expected to be explosive based on chemical structure
Oxidising Properties	Not determined	Not expected to be oxidising based on chemical structure

* For the notified polymer at ≤ 75% concentration in solvent solution.

DISCUSSION OF PROPERTIES

Reactivity
The notified polymer is contained as a solute in naptha which can react violently if exposed to oxidising agents. Mixture is stable under normal conditions.

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

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as a component of diesel fuel additive packages at ≤ 75% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 10	< 15	< 20	< 30	< 50

PORT OF ENTRY
Melbourne, Sydney, Brisbane and Perth

TRANSPORTATION AND PACKAGING
The notified polymer will be imported as part of diesel fuel additive packages contained in intermediate bulk containers (IBC) or ISO Intermodal Containers.

USE
The notified polymer will be used as a diesel fuel additive at ≤ 0.02% concentration.

OPERATION DESCRIPTION
The additive mixture (containing the notified polymer at ≤ 75% concentration) will be added to fuel by continuous injection into the fuel storage tank at the refinery and/or fuel distribution terminal. Diesel fuel containing the notified polymer (at ≤ 0.02% concentration) will then be transported to fuel retail stations.

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)*
Stevedore	1	1 – 2
Formulator	2	6 – 8
Quality Control Analyst	2	6 – 8
Transport Workers	10 – 20	6 – 8
Point of Sale Workers	< 1	8 - 12

EXPOSURE DETAILS

The potential routes of occupational exposure are dermal and ocular. Inhalation exposure is not expected as the polymer is expected to have a low vapour pressure and the generation of mists or aerosols is not expected.

Transport and storage

Transport workers are not expected to be exposed to the imported product containing the notified polymer at ≤ 75% concentration, as they will be handling closed containers. Dermal or ocular exposure is possible in the event of an accident where the packaging is breached or during transfer to storage tanks.

Blending

At the fuel manufacturer's refinery terminal, blending of the notified polymer with fuel will be carried out automatically in a closed system through volumetric injection of the additive package (containing the notified polymer at ≤ 75% concentration) into tank trucks. Exposure to the notified polymer may occur from accidental spillage or through the handling of feed couplings involved in the transfer of the fuel additive containing the notified polymer. Exposure is expected to be low and further reduced by adequate ventilation and workers wearing personal protective equipment when handling fuel.

Worker exposure to the notified polymer at ≤ 0.02% concentration may also occur during sampling and analysis of blended fuel at the refinery or during maintenance of refinery plant or pipelines. The exposure would be limited by appropriate personal protective equipment worn by workers.

Transport and storage of fuel

Dermal or ocular exposure to drips and spills of fuel containing the notified polymer at ≤ 0.02% concentration is possible during the connection and disconnection of transfer hoses. Exposure is expected to be limited during transportation as the protocols of loading and unloading are done with minimal spills. The drivers also usually wear appropriate personal protective equipment when unloading the fuel.

End users of fuel

Personnel from commercial trucking fleet, users of off road vehicles and users of agriculture equipment may be exposed to fuel containing the notified polymer at up to 0.01% concentration during handling and fuelling of the vehicles.

6.1.2. Public Exposure

The public will not have exposure to the imported product containing the notified polymer at ≤ 75% concentration as it will be used in industrial settings.

The public may have incidental skin or eye contact with fuel containing the notified polymer at ≤ 0.02% concentration through operations such as refilling vehicles

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer. The results from toxicological investigations conducted on close analogues of the notified polymer (analogue 1 and analogue 2) are summarised in the table below. Analogue 1, analogue 2 and the notified polymer are considered to be very similar in chemical composition and therefore the endpoints presented below are likely to reflect the toxicity of the notified polymer. Details of the studies of analogue 1 and analogue 2 can be found in Appendix A.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity[1]	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation[1]	slightly irritating
Rabbit, eye irritation[1]	slightly irritating
Guinea pig, skin sensitisation – adjuvant test[2]	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation[3]	non mutagenic

[1]Test substance: Analogue 1 at 70% concentration
[2]Test substance: Analogue 1 at 90% concentration
[3]Test substance: Analogue 2

Toxicokinetics.
Dermal absorption of the notified polymer is likely to be limited, based on the relatively high molecular weight (> 500 Da) and expected low water solubility. Given there are significant levels of low molecular weight species < 500 Da, the possibility of absorption via the gastrointestinal tract cannot be ruled out.

Acute toxicity.
Analogue 1 at 70% concentration is of low acute oral toxicity in rats.

No acute dermal toxicity studies were provided for the notified polymer or for the close analogues 1 and 2. Toxicity by the dermal route is not expected given the limited potential for the notified polymer to be dermally absorbed and the absence of any structural alerts of concern.

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

Irritation and sensitisation.
Analogue 1 at 70% concentration is slightly irritating to the eye and skin of rabbits. In the skin irritation study, slight irritation was observed in all animals at the 24-hour observation period that was resolved at the 48-hour observation period. In the eye irritation study, slight to moderate conjunctival irritation was observed in all animals that persisted up to the 4-day observation period. All animals showed full recovery 7 days after exposure.

Analogue 1 showed no evidence of sensitisation in a Guinea Pig maximisation test at a challenge concentration of 90%.

Repeated dose toxicity.
No repeated dose toxicity studies were provided for the notified polymer or for the close analogues 1 and 2. The main route for exposure to the notified polymer is dermal. Given the limited potential for the notified polymer to be dermally absorbed and the absence of any structural alerts of concern, systemic toxicity by the dermal route is not expected.

Mutagenicity/Genotoxicity.
Analogue 2 was not mutagenic in a bacterial reverse mutation test with or without metabolic activation.

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the available information, the notified polymer is expected to be of low hazard presenting only as a slight skin and eye irritant. Workers may be exposed to the notified polymer at up to 75% concentration. At

such high concentrations workers may be at risk of slight skin and eye irritating effects. Therefore, safe work practices should be in place to minimise skin and eye contact when handling fuel additive packages containing the notified polymer at high concentrations. The expected use of personal protective equipment (gloves, coveralls and safety glasses/goggles) is expected to further reduce the risk of irritating effects.

Therefore, given the use of sufficient workplace controls, the risk to workers from use of the notified polymer is not considered unreasonable.

6.3.2. Public Health

Based on the available information, the notified polymer is expected to be of low hazard presenting only as a slight skin and eye irritant.

The public may be exposed to the notified polymer at ≤ 0.02% concentration in fuel. Given the low use concentration and expected low hazard of the notified polymer, the risk to the public from the use of the notified polymer is not expected 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 imported into Australia for use as an additive in diesel fuel. No significant release of the notified polymer is expected from transportation and storage.

Blending of the additive containing the notified polymer into diesel fuels will occur in well-controlled industrial facilities. Minimal release of the notified polymer into the environment is expected as blending occurs in fully enclosed automated systems with fixed transfer lines. Accidental spills and leaks during transport and normal blending and packaging procedures will be contained and collected for disposal to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

When used as an additive in diesel fuel, the majority of the notified polymer will be consumed during the combustion of the fuel by vehicles or machinery.

RELEASE OF CHEMICAL FROM DISPOSAL

Waste water from the cleaning of the import containers and storage vessels is expected to be collected by an approved waste management company and flocculated, with solids generated to be disposed of to landfill or by incineration in accordance with local government regulations. Release of the notified polymer to surface water is expected to be negligible.

7.1.2. Environmental Fate

Most of the notified polymer in diesel fuel will be consumed and thermally decomposed during use.

Minor amounts of the notified polymer are expected to be disposed to landfill as residues in containers or collected waste. Given that the notified polymer is expected to adsorb strongly to soils and its low water solubility, the notified polymer sent to landfill is expected to be immobile. Based on the biodegradability of an analogue polymer (Analogue 1), the notified polymer is not expected to be readily biodegradable (8% in 28 days for the analogue). However, bioaccumulation of the notified polymer is unlikely as it is not expected to cross biological membranes due to its high molecular weight and low water solubility. In landfill, the notified polymer is expected to eventually degrade via abiotic and biotic 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)

As significant aquatic exposure is not expected at any stage of the notified polymer's life-cycle within Australia, the predicted environmental concentration (PEC) has not been calculated.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymer. However, ecotoxicological investigations conducted on an analogue (Analogue 1) of the notified polymer have been provided for daphnia and algae, and the results are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity	48 h EL50 > 100 mg/L (WAF)	Not harmful to daphnids (acute)
	48 h NOEL = 100 mg/L (WAF)	Not harmful to daphnids (chronic)
Algal Toxicity	72 h E_rL50 > 160 mg/L (WAF)	Not harmful to algae (acute)
	72 h NOE_rL = 160 mg/L (WAF)	Not harmful to daphnids (chronic)

Analogue 1 and the notified polymer share the same core structure, differing only in the length of the alkyl sidechains. Both ecotoxicity studies were conducted using a water accommodated fraction of Analogue 1. No significant adverse effects were observed in any of the provided tests. These results are supported by the estimated ecotoxicological endpoints for the notified polymer using ECOlogical Structure-Activity Relationships (ECOSAR 1.11, EPI Suite 4.1) (US EPA, 2011), which predicts that the notified polymer is not harmful to aquatic organisms up to the limit of its solubility in water for acute and chronic endpoints.

It is concluded that the analogue, and by inference the notified polymer, is not expected to be harmful to aquatic life up to the limit of its solubility in water. 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 effects.

7.2.1. Predicted No-Effect Concentration

As no significant adverse effects were observed in any of the ecotoxicity tests submitted and modelled, the predicted no-effect concentration has not been calculated, as this concentration would be significantly greater than the notified polymer's solubility in water.

7.3. Environmental Risk Assessment

The calculation of the Risk Quotient (Q = PEC/PNEC) was not possible as the PEC and PNEC were not calculated. The notified polymer is not expected to pose an unreasonable risk to the environment based on the assessed use pattern indicating low potential for release to the aquatic environment, and the absence of any observed ecotoxicological effects to aquatic organisms.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE	Analogue 1 (70% concentration)
METHOD	EC Directive 92/69/EEC B.1bis Acute Toxicity (Oral) Fixed Dose Method.
Species/Strain	Rat/Sprague-Dawley
Vehicle	1% w/v aqueous methylcellulose
Remarks - Method	Composition of test substance was 70% analogue polymer and 30% polyisobutylene. No protocol deviations.

RESULTS

Sighting Study

Dose mg/kg bw	*Administered*	*Evident Toxicity*	*Mortality*
2000	1 F	None	0
500	1 F	None	0

Signs of Toxicity	Not provided in study report
Effects in Organs	Not provided in study report

Main Study

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

Discriminating Dose	2000 mg/kg bw
Signs of Toxicity	No signs of systemic toxicity.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	In all animals, piloerection was observed within five minutes of dosing and persisted through to Day 3. No other clinical signs observed and recovery was complete by Day 4. All animals showed expected gains in bodyweight.
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Huntingdon Life Sciences (1996a)

A.2. Irritation – skin

TEST SUBSTANCE	Analogue 1 (70% concentration)
METHOD	EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (1 M, 2 F)
Vehicle	None
Observation Period	3 days
Type of Dressing	Semi-occlusive.
Remarks - Method	Composition of test substance was 70% analogue polymer and 30% polyisobutylene. No protocol deviations. Exposure period for all animals was 4 hours.

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	0.3	0.3	0.3	1	< 48 h	0
Oedema	0	0	0.3	1	< 48 h	0

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

Remarks - Results: After 24 hours, all animals exhibited very slight erythema, with one animal exhibiting very slight oedema as well. Full recovery was observed in all animals 48 hours after exposure. No signs of toxicity or ill health were observed in any of the animals.

CONCLUSION: The test substance is slightly irritating to the skin.

TEST FACILITY: Huntingdon Life Sciences (1996b)

A.3. Irritation – eye

TEST SUBSTANCE: Analogue 1 (70% concentration)

METHOD: EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).
Species/Strain: Rabbit/New Zealand White
Number of Animals: 3 (1 M, 2 F)
Observation Period: 7 days
Remarks - Method: Composition of test substance was 70% analogue polymer and 30% polyisobutylene. Conjunctiva discharge was not recorded in the study. There were no other protocol deviations. One animal was initially treated to check severity of response. Observations were taken at 1, 24, 48 and 72 hours, and 4 and 7 days post-exposure.

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	1.3	1	1	2	< 7 days	0
Conjunctiva: chemosis	0.7	1	0	1	< 7 days	0
Corneal opacity	0	0	0	0	NA	0
Iridial inflammation	0	0	0	0	NA	0

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

Remarks - Results: No corneal or iridial inflammation was observed. A diffuse crimson colouration of the conjunctivae with eyelid swelling was observed for two animals (1 hour after exposure), with the effects maintained in one after 24 hours, and full recovery from eyelid swelling in the other. All animals exhibited hyperaemic vessels for at least 4 days. Eyelid swelling was observed for 48 hours in one animal and up to 4 days in another. All animals showed full recovery 7 days after exposure. No other signs of toxicity or ill health were observed in any of the animals.

CONCLUSION: The test substance is slightly irritating to the eye.

TEST FACILITY: Huntingdon Life Sciences (1996c)

A.4. Skin sensitisation

TEST SUBSTANCE	Analogue 1 (90% concentration)
METHOD	EC Directive 96/54/EC B.6 Skin Sensitisation – Magnusson and Kligman
Species/Strain	Guinea pig/Dunkin/Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 100%
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: Intradermal: 30% w/v in Alembicol D Topical: 100%
Signs of Irritation	Intradermal injections: necrosis was observed at sites receiving Freund's Complete Adjuvant in test and control animals. Slight irritation was seen in test animals at sites receiving the analogue polymer 30% w/v in Alembicol D and slight irritation was observed in control animals receiving Alembicol D. Topical application: Slight erythema was observed in test animals following topical application with the test substance as supplied. Slight erythema was also seen in the control animals.
CHALLENGE PHASE	
1st challenge	Topical: 100% and 50% w/v in Alembicol D
2nd challenge	Not conducted
Remarks - Method	Composition of test substance was 90% analogue polymer and 10% polyisobutylene. Six days after the injections all animals were treated with 10% sodium lauryl sulphate in petrolatum.

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	0	-	-
	50%	0	0	-	-
Control Group	100%	0	0	-	-
	50%	0	0	-	-

Remarks - Results	No signs of ill health or toxicity were recorded. All animals recorded an increase in bodyweight over the period of the study. Challenge: No dermal reactions were seen in any of the test or control animals.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.
TEST FACILITY	Huntingdon Life Sciences (1996d)

A.5. Genotoxicity – bacteria

TEST SUBSTANCE	Analogue 2
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure.
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA$^-$
Metabolic Activation System	S9 mix from phenobarbitone/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 50 - 5000 µg/plate b) Without metabolic activation: 50 - 5000 µg/plate
Vehicle	Dimethyl sulphoxide.
Remarks - Method	No protocol deviation.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	> 5,000			
Test 1		> 5,000	> 5,000	negative
Test 2		> 5,000	> 5,000	negative
Present	> 5,000			
Test 1		> 5,000	> 5,000	negative
Test 2		> 5,000	> 5,000	negative

*Slight, greasy film observed at 5,000 µg/plate

Remarks - Results

In the preliminary toxicity test, the test material was not toxic to the bacterial background lawns of the bacteria used (TA100 and WP2uvrA$^-$). However, TA100 exhibited decreases in revertant colony frequency at the maximum concentrations of the test material.

The test material caused no visible reduction in the growth of the bacterial background lawn at any dose level and was, therefore, tested up to the maximum recommended dose level of 5000 µg/plate. However, several strains exhibited decreases in revertant colony frequency. A slight, greasy film was observed at 5000 µg/plate, this observation did not prevent the scoring of revertant colonies.

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

All of 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	Harlan (2009a)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Environmental Fate

B.1.1. Ready biodegradability

TEST SUBSTANCE: Analogue 1.

METHOD: OECD TG 301 B Ready Biodegradability: CO2 Evolution Test.
- Inoculum: Activated sludge from the aerated stage of a local domestic wastewater treatment plant (Leicestershire, UK).
- Exposure Period: 28 days.
- Auxiliary Solvent: None.
- Analytical Monitoring: TOC.
- Remarks - Method: No significant deviation from the protocol was found.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
0	0	0	0
2	7	2	47
6	9	6	62
8	11	8	65
10	14	10	66
14	13	14	70
21	14	21	88
28	9	28	88
29*	8	29*	89

*Day 29 values were corrected to include any carry-over of CO_2 detected in Absorber 2.

- Remarks - Results: All validity criteria for the test were satisfied. The percentage degradation of the reference compound, sodium benzoate (70%), surpassed the threshold level of 60% by 14 days. Therefore, the test indicates the suitability of the inoculums. The test substance is considered to be an acceptable analogue of the notified polymer for this property. The toxicity control exceeded 40% biodegradation after 14 days, showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the analogue polymer after 28 days was 8%. Therefore, the test substance cannot be classified as readily biodegradable according to the OECD (301B) guideline.

CONCLUSION: The test substance, and hence the notified polymer, are not readily biodegradable.

TEST FACILITY: Harlan (2009d)

B.2. Ecotoxicological Investigations

B.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE: Analogue 1.

METHOD: OECD TG 202 Daphnia sp. Acute Immobilisation 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 substance was prepared as a Water Accommodated Fraction

(WAF) due to its low water solubility. No significant deviation from the protocol was found.

RESULTS

Concentration (filtered WAF; mg/L)		*Number of D. magna*	*Cumulative Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	Control	20	0	0
100	0.74-1.1	20	0	0

EL50 > 100 mg/L (WAF) at 48 hours.
NOEL 100 mg/L (WAF) at 48 hours.
Remarks - Results All validity criteria for the test were satisfied. The actual concentrations of the test substance in WAFs were measured at 0 and 48 hours within the 48 h test period. The test solutions were renewed every 24 hours during the 48 h test period. The test substance is considered to be an acceptable analogue of the notified polymer for the toxicity to *Daphnia*. The 48 h EL50 determined based on the time weighted means of measured concentrations was greater than 1.1 mg/L, and correspondingly the NOEL was equal to 1.1 mg/L.

CONCLUSION Under the conditions of the study, the test substance, and hence the notified polymer, are not harmful to daphnids up to the limit of its water solubility.

TEST FACILITY Harlan (2009b)

B.2.2. Algal growth inhibition test

TEST SUBSTANCE Analogue 1.

METHOD OECD TG 201 Freshwater Alga, Growth Inhibition Test.
Species *Desmodesmus subspicatus*.
Exposure Period 72 hours.
Concentration Range Nominal: 100 mg/L (loading rate).
Actual: 0.04 mg/L.
Auxiliary Solvent None.
Water Hardness Not reported.
Analytical Monitoring HPLC-MS.
Remarks - Method The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. No significant deviation in protocol.

RESULTS

Biomass (filtered WAF)		*Growth (filtered WAF)*	
E_bL50	*NOE_bL*	*E_rL50*	*NOE_rL*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
> 160	160	> 160	160

Remarks - Results All validity criteria for the test were satisfied. The actual concentrations of the test substance in WAFs were measured at 0 and 72 hours within the 72 h test period. The test substance is considered to be an acceptable analogue of the notified polymer for the toxicity to algae. No effects were observed.

CONCLUSION Under the study conditions, the test substance, and hence the notified polymer, are not harmful to alga up to the limit of its water solubility.

TEST FACILITY Harlan (2009c)

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