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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Ethyltrimonium Chloride Methacrylate/Hydrolyzed Wheat Protein Copolymer

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

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 SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1602	Croda Singapore Pty Ltd (trading as Croda Australia)	Ethyltrimonium Chloride Methacrylate/Hydrolyzed Wheat Protein Copolymer	ND*	≤100 tonnes per annum	Component of hair care products

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the limited data provided, the notified polymer is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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

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

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

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation processes:
  - Enclosed, automated processes, where possible.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer during reformulation processes:
  - Avoid contact with skin and eyes.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during reformulation processes:
  - Coveralls, impervious gloves, goggles.

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

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

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
- the polymer has a number-average molecular weight of less than 1000;
- the method of manufacture of the notified polymer changes, such that a significant proportion of low molecular weight species (<1000 Da) will be present;
- the notified polymer is intended for use in cosmetic products to be applied by spray;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of hair care products or is likely to change significantly;
- the amount of polymer being introduced has increased from 100 tonnes per annum, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicant(s)
Croda Singapore Pty Ltd, trading as Croda Australia (ABN: 34 088 345 457)
Suite 102, 447 Victoria St,
Wetherill Park, NSW 2164

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number,

molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymer in Voluminus (<25% notified polymer)

OTHER NAME(S)
Ethyltrimonium Chloride Methacrylate/Hydrolyzed Wheat Protein Copolymer (INCI Name)

MOLECULAR WEIGHT
Mn >10,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >90%

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	The notified polymer will be introduced in an aqueous solution and will not be isolated.
Boiling Point	Not determined	The notified polymer will be introduced in an aqueous solution and will not be isolated.
Density	Not determined	The notified polymer will be introduced in an aqueous solution and will not be isolated.
Vapour Pressure	Not determined	Based on the high molecular weight, vapour pressure is expected to be low.
Water Solubility	Not determined	The notified polymer is expected to be water soluble based on the presence of hydrophilic groups.
Hydrolysis as a Function of pH	Not determined	The notified polymer contains functional groups that may hydrolyse. However, significant hydrolysis is not expected to occur in the environmental pH range of 4-9.
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is not expected to partition significantly to octanol from water phase based on the presence of hydrophilic groups.
Adsorption/Desorption	Not determined	The notified polymer is expected to have strong potential to adsorb to sediment soil due to the presence of cationic functional groups.
Dissociation Constant	Not determined	The notified polymer is expected to be ionised in the environmental pH range of 4-9 with the presence of cationic functional groups.
Flash Point/Flammability	Not determined	The notified polymer will be introduced in an aqueous solution and will not be isolated.
Autoignition Temperature	Not determined	The notified polymer will be introduced in an aqueous

		solution and will not be isolated.
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

*Imported product containing the notified polymer at <25%

DISCUSSION OF PROPERTIES

Reactivity

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

Dangerous Goods classification

Based on the submitted physico-chemical data in the above table, the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported at <25% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤100	≤100	≤100	≤100	≤100

PORT OF ENTRY

Sydney, Melbourne, Brisbane, Perth

IDENTITY OF RECIPIENTS

Croda Australia

TRANSPORTATION AND PACKAGING

The notified polymer will be transported by road or rail to the notifier's warehouse and/or to reformulation sites in sealed 25 kg (or 5 kg) plastic drums. The end-use products will be packaged in containers suitable for retail sale.

USE

The notified polymer will be used as a component (≤5%) of leave-on and rinse-off hair care products. The notified polymer will not be used in products that will be applied by spray.

OPERATION DESCRIPTION

The procedures for incorporating the imported product (containing <25% notified polymer) into end-use products will likely vary depending on the nature of the hair care product formulated, and may involve both automated and manual transfer steps. However, in general, it is expected that the reformulation processes will involve blending operations that will be highly automated and occur in an enclosed environment, followed by automated filling of the reformulated products into containers of various sizes.

The finished products containing the notified polymer (at ≤5% concentration) may be used by consumers and professionals such as hairdressers.

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)*
Distribution (Storage & Transport)	6	240
Formulation	6	240
Point of Sale	6	240
Salon Workers	Unspecified	Unspecified

EXPOSURE DETAILS

Transport and Storage
Transport and storage workers may only come into contact with the notified polymer (at <25% concentration) in the event of an accidental rupture of containers.

Reformulation
Workers involved in reformulation processes may be exposed to the notified polymer (at <25% concentration) via the dermal and ocular routes during transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. However, exposure is expected to be minimised through the use of mechanical ventilation and/or enclosed systems and through the use of personal protective equipment (PPE), such as coveralls, goggles and impervious gloves.

Use of finished hair care products
Exposure to the notified polymer in end-use products (at ≤5% concentration) may occur in professions where the services provided involve the application of the hair care products to clients (e.g. hairdressers). Such professionals may use some personal protective equipment to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified polymer.

6.1.2. Public Exposure
The general public will be repeatedly exposed to the notified polymer (at ≤5% concentration) through the use of the leave-on and rinse-off hair care products. While the principal route of exposure will be dermal, ocular exposure is also possible.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix A.

Endpoint	*Result and Assessment Conclusion*
Human, skin irritation	non-irritating
Human, eye irritation	non-irritating
Mutagenicity – bacterial reverse mutation	non-mutagenic

Given the high molecular weight of the notified polymer (MW>10,000 Da), dermal absorption and passive diffusion of the notified polymer across the gastrointestinal tract (GI tract) is expected to be limited. In addition, absorption of low molecular weight species is not expected (negligible proportion <1000 Da).

The notified polymer (at <25% concentration) was not irritating in an in vitro skin irritation study (EpiSkin reconstructed human epidermis). The notified polymer (at <25% concentration) was also determined by the study authors to be non-irritating in an in vitro eye irritation study (SkinEthic reconstructed human corneal epithelium model). In addition, the notified polymer was not mutagenic in a bacterial reverse mutation study.

It is noted that the in vitro eye irritation method has not been validated for regulatory purposes. In addition, it is noted that information on the skin sensitisation potential and acute/repeated dose toxicity effects of the notified polymer has not been provided. However, based on the high molecular weight of the notified polymer (and absence of low molecular weight species) and the expected limited dermal absorption, acute and/or repeated dose toxicity effects are not expected from use of the polymer.

Health hazard classification
Based on the limited data provided, the notified polymer is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Reformulation
The notified polymer may be handled by workers at <25% concentration during reformulation tasks. At such concentrations, acute and/or repeated dose toxicity effects are not expected. However, given the absence of supporting toxicity studies, steps should be taken (e.g. use of PPE: coveralls, goggles and impervious gloves) to minimise exposure to notified polymer. Therefore, the risk to workers associated with use of the notified polymer is not considered to be unreasonable.

Use of finished hair care products
Hair care professionals may handle the notified polymer at ≤5% concentration in leave-on and rinse-off hair care products, similar to public use. Therefore, the risk to workers who regularly use the notified polymer is expected to be of a similar or lesser extent than that experienced by members of the public who will use such products on a regular basis. For details of the public health risk assessment, see section 6.3.2.

Based on the information available, the risk to workers associated with use of the notified polymer at ≤5% concentration in leave-on and rinse-off hair care products is not considered to be unreasonable.

6.3.2. Public Health
Members of the public may experience widespread and frequent exposure to the notified polymer (at ≤5% concentration) through the daily use of cosmetic products which will be applied directly to the hair. At such concentrations, acute and/or repeated dose toxicity effects are not expected. Therefore, the risk to the public associated with the use of the notified polymer at ≤5% concentration in leave-on and rinse-off hair care products is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will be imported into Australia in an aqueous solution as a component of cosmetic hair care products. The release of the notified polymer to the environment during importation, storage, and transport is unlikely.

An estimated 1% of the annual import volume of notified polymer (1000 kg) may be lost as spillages during reformulation. The spillages are expected to be absorbed using suitable materials and disposed of to landfill. Less than 1% of the notified polymer is estimated to remain as residues in import containers that will be disposed of to landfill. Waste water generated from equipment washing is estimated to contain up to 1% of the notified polymer. These washes are expected to be treated accordingly and the sludge containing the notified polymer will be collected for disposal to landfill.

RELEASE OF CHEMICAL FROM USE
As the notified polymer will be used in leave-onand rinse-off hair care products, it is expected that the vast majority of notified polymer will be released to sewerage as a result of application in both the professional and at home settings.

RELEASE OF CHEMICAL FROM DISPOSAL
The unused notified polymer (residues in containers) is expected to be disposed of to landfill with the containers.

7.1.2. Environmental Fate

No environmental fate data were submitted. The notified polymer is not expected to be bioaccumulative based on its high molecular weight of >10,000. Given the use pattern of the notified polymer in cosmetic hair care products, 100% release of the polymer to sewer is expected for the worst case scenario consideration. In a sewage treatment plant (STP), 90% of the notified polymer is expected to be adsorbed on sludge (US EPA, 1982) and disposed of to landfill. A small amount (up to 10%) of the notified polymer is expected to be released to surface water via the STP effluent. Leaching of the notified polymer in landfill is possible given it is soluble in water. However, this is expected to be slow considering the strong adsorption of the polymer to soil due to the presence of cationic groups. In both water and landfill, the notified polymer is expected to slowly degrade via biotic and abiotic pathways, forming water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentrations (PECs) of the notified polymer in aquatic environment have been calculated assuming 100% release of the notified polymer to sewer. Considering the presence of cationic functional groups and the molecular weight of >10,000, 90% removal of the notified polymer in a sewage treatment plant has been used in the calculation (US EPA, 1982).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	100,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of polymer released to sewer	100,000	kg/year
Days per year where release occurs	365	days/year
Daily polymer release:	273.97	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	Mitigation
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	6.06	µg/L
PEC - Ocean:	0.61	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 545.2 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified polymer may approximate 3.6 mg/kg in applied soil. This assumes that degradation of the notified polymer occurs in the soil within 1 year from application. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated biosolids application, the concentration of notified polymer in the applied soil in 5 and 10 years may approximate 18.2 mg/kg and 36.35 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted.

Ecotoxicological endpoints for the notified polymer were calculated based on SAR equations assuming a worst case cation charge density for the polymer (Boethling and Nabholz, 1997). The % a-N is calculated to be >3.5 for the polymer part without the natural polymer (i.e. 100% cation charge density for the polymer), which is for the worst case consideration. The endpoints for aquatic life are calculated and summarised in the table below after having been modified by mitigation factors to account for the anticipated binding of the polymer with organic carbon in surface waters:

Calculated Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 = 30.8 mg/L	Harmful
Daphnia Toxicity	48 h EC50 = 11 mg/L	Harmful
Algal Toxicity	96 h EC50 = 4.4 mg/L	Toxic

The notified polymer is potentially moderately toxic to aquatic organisms in environmental waters with typical levels of total organic carbon. The SAR estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the polymer. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified polymer to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

Predicted No-Effect Concentration (PNEC) for the aquatic compartment has been calculated based on the predicted most sensitive endpoint for algae. An assessment factor of 500 was used given the endpoints were calculated using SAR equations:

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Green algae).	4.4	mg/L
Assessment Factor	500	
PNEC:	8.8	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) has been calculated using the calculated PEC and PNEC:

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	6.06	8.8	0.688
Q - Ocean:	0.61	8.8	0.069

The Q values for both river and ocean water are calculated to be <1. Based on the calculated Q values, no unreasonable risk is expected from the assessed use of the notified polymer. For PBT consideration, the notified polymer may be persistent due to the presence of the non-natural part of the polymer. It is not considered to meet the criterion for bioaccumulation given the high molecular weight of >10,000 Da. It is not considered to meet the criterion for toxicity since it is predicted to be moderately toxic to aquatic life based on worst case consideration.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Irritation – skin (in vitro)

TEST SUBSTANCE	Notified polymer (<25%)
METHOD	Similar to OECD TG 439 *In Vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method EpiSkin™ Reconstituted Human Epidermis Model
Vehicle	None
Remarks - Method	The test substance (10 µL) was applied to the tissues in triplicate. Following 15 minute exposure periods, the tissues were rinsed and then incubated at 37 °C for approximately 42 hours. Following treatment with MTT [3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide; 0.3mg/mL], the tissues were incubated at 37 °C for 3 hours. Positive (sodium dodecyl sulphate; 5%) and negative (phosphate buffered saline) controls were run in parallel with the test substance. The optical densities were determined at 540 nm.

RESULTS

Test Material	*Mean OD_{540} of triplicate tissues*	*± SD of OD_{540}*	*Relative mean viability (%)*	*± SD of relative mean viability (%)*
Negative Control	0.904	0.053	100*	5.9
Positive Control	0.054	0.009	6.0	1.0
Test Substance	0.884	0.053	97.8	5.8

OD = optical density; SD = standard deviation
*The mean viability of the negative control tissues is set as 100%.

Remarks - Results	The relative mean viability of the test substance treated tissues was 97.8% after a 15-minute exposure period. The positive and negative controls gave satisfactory results, confirming the validity of the test system.
CONCLUSION	The notified polymer was considered to be non-irritating to the skin.
TEST FACILITY	Harlan (2009a)

A.2. Irritation – eye (in vitro)

TEST SUBSTANCE	Notified polymer (<25%)
METHOD	Determination of Ocular Irritation Potential Using the SkinEthic Reconstituted Human Corneal Epithelium Model
Remarks - Method	The test substance (30µL) was applied to the tissues in triplicate. Following 10 minute exposure periods, the tissues (2/group, with the others being retained for histopathology if necessary) were rinsed and then treated with MTT [3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide; 0.5 mg/mL; incubation period of 3 hours at 37 °C]. Following extraction, the optical densities were determined (540 nm). Positive (sodium dodecyl sulphate; 1%) and negative controls were run in parallel with the test substance.

The test substance was considered by the study authors to be an irritant if the relative mean tissue viability was <60%.

RESULTS

Test Material	*Mean OD_{540} of duplicate tissues*	*Relative mean viability (%)*
Negative Control	0.941	100*
Positive Control	0.218	23.2
Test Substance	0.812	86.3

OD = optical density
*The mean viability of the negative control tissues is set as 100%.

Remarks - Results: The relative mean viability of the test substance treated tissues after a 10-minute exposure period was 86.3%.

CONCLUSION: The notified polymer was considered to be non-irritating to the eyes.

TEST FACILITY: Harlan (2009b)

A.3. Genotoxicity – bacteria

TEST SUBSTANCE: Notified polymer (<25%)

METHOD: OECD TG 471 Bacterial Reverse Mutation Test
EC Directive 2008/440/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation and pre incubation procedures

Species/Strain: *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA$^-$

Metabolic Activation System: Phenobarbitone/β-naphthoflavone-induced rat liver (S9 homogenate)

Concentration Range in Main Test: a) With metabolic activation: 150-5000 µg/plate
b) Without metabolic activation: 150-5000 µg/plate

Vehicle: Sterile distilled water

Remarks - Method: A preliminary toxicity test (0-5000 µg/plate) was performed to determine the toxicity of the test material (TA100 and WP2uvrA$^-$ only).

Tests 1 (plate incorporation method) and 2 (pre-incubation method) were conducted on separate days using fresh cultures of the bacterial strains and fresh test material formulations.

Vehicle and positive controls were used in parallel with the test material.
Positive controls: i) without S9: N-ethyl-N'-nitro-N-nitrosoguanidine (TA100, TA1535, WP2uvrA$^-$), 9-aminoacridine (TA1537) and 4-nitroquinoline-1-oxide (TA98); ii) with S9: 2-aminoanthracene (TA100, TA1535, TA1537, WP2uvrA$^-$) and benzo(a)pyrene (TA98).

Based on the results of tests 1 and 2 (see remarks below) a third confirmatory test was conducted using strain TA100 (with and without S9; plate incorporation and pre-incubation methods).

RESULTS

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

Remarks - Results	The test substance did not cause a visible reduction in the growth of the bacterial background lawn at any dose level. No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains up to and including the maximum dose, either with or without metabolic activation. Statistically significant (reproducible) increases in the TA100 colony frequency were noted at the upper dosage levels in all tests (including the confirmatory assay), with and without metabolic activation. These increases were not considered by the study authors to be biologically relevant, as the maximum fold increase over controls did not exceed twofold at any time. The measured levels were also within the in-house historical untreated/vehicle control maxima and the specified range for the tester strain. The positive controls gave satisfactory responses, confirming the validity of the test system.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Harlan (2010)

BIBLIOGRAPHY

Harlan (2009a) (Notified polymer): Determination of Skin Irritation Potential Using the EpiSkin™ Reconstituted Human Epidermis Model (Project No. 2724/0013, December, 2009). Derbyshire, U.K., Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2009b) (Notified polymer): Assessment of Ocular Irritation Potential Using the SkinEthic Reconstituted Human Corneal Epithelium Model (Project No. 2724/0012, December, 2009). Derbyshire, U.K., Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Harlan (2010) (Notified polymer): Reverse Mutation Assay "AMES Test" Using *Salmonella typhimurmium* and *Escherichia coli* (Project No. 2724/0054, August, 2010). Derbyshire, U.K., Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia

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 >.

US EPA (1982) Fate of Priority Pollution in Publicly Owned Treatment Works, US EPA Report No. 440/1-82-303. P 203, in Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, Hamilton, J.D. and R. Sutcliffe (eds.).

Boethling, R.S. and V.J. Nabholz (1997). Environmental Assessment of polymers under the U.S. Toxic Substances Control Act, pp. 187-234, in Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, Hamilton, J.D. and R. Sutcliffe (eds.).