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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

PUBLIC REPORT

MODISURF™-LQ-(MV)

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

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

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**Director
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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1983	Croda Singapore Pte Ltd (trading as Croda Australia)	MODISURF™-LQ-(MV)	ND*	≤ 3 tonnes per annum	Additive in household cleaners

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

<i>Hazard classification</i>	<i>Hazard statement</i>
Acute Category 1	H400-Very toxic to aquatic life
Chronic Category 1	H410-Very toxic to aquatic life with long lasting effects

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

- 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, noting that the formulations may be classified because of hazardous impurities.

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(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1,000;
 - the final concentration of the notified polymer exceeds or is planned to exceed 5% in end-use productsor
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from additive in household cleaners, 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

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT

Croda Singapore Pte Ltd (trading as Croda Australia) (ABN: 34 088 345 457)
Suite 102, Level 1, 447 Victoria Street
WETHERILL PARK NSW 2164

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular formula and detailed structural formula, molecular weight, analytical data, polymer constituents, residual monomers, impurities, additives/adjuvants and use details.

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

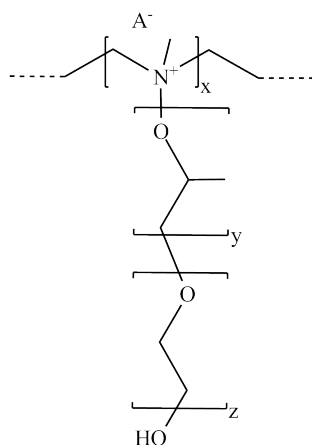
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

MODISURF™-LQ-(MV)

STRUCTURAL FORMULA



Generic structure of MODISURF group of polymers

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference GPC was provided.

3. COMPOSITION

DEGREE OF PURITY

> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: cloudy yellow liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Notified polymer is liquid at room temperature
Boiling Point	Not determined	-
Density	~ 1,004 kg/m ³	Estimated by notifier
Vapour Pressure	Not determined	Expected to be low based on the high molecular weight of the notified polymer
Water Solubility	Not determined	The notified polymer is expected to be at least water miscible based on its predominately hydrophilic functional groups and surface activity.
Hydrolysis as a Function of pH	Not determined	The notified polymer contains functional groups which are expected to hydrolyse under the environmental pH range (4–9) at ambient temperatures
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is surface active and will tend to accumulate at the phase interface of octanol and water
Adsorption/Desorption	Not determined	The notified polymer is expected to adsorb to soil and sediment based on surface activity
Dissociation Constant	Not determined	The notified polymer contains cationic functionalities and is likely to be ionised in the environmental pH range (4 - 9)
Flash Point	> 100 °C	SDS
Autoignition Temperature	Not determined	Expected to be high, on basis of flash point
Explosive Properties	Not determined	The notified polymer contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	The notified polymer 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 limited physico-chemical data, 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 in neat form for formulation in to domestic cleaning products in Australia. It may also be imported in end-use products.

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

Year	1	2	3	4	5
Tonnes	3	3	3	3	3

PORT OF ENTRY

Melbourne, Perth, Sydney

TRANSPORTATION AND PACKAGING

The notified polymer will be imported in 50 kg plastic containers. It will be transported from the port of entry to the site of storage/formulation by road and/or railway.

USE

The notified polymer will be used as a component of wash off shower cleaning products for domestic use. The final concentration of the notified polymer in the products will be less than 5%.

OPERATION DESCRIPTION

The notified polymer will not be manufactured in Australia. It will be imported in neat form and formulated in Australia for use in domestic cleaning products.

At the reformulation site, the notified polymer will be formulated into household cleaning products. It will be weighed and added to blending equipment manually. Samples may be collected during the blending process for quality control testing. After blending, the cleaning product will be packaged into appropriate containers and stored in the facility till they are distributed to retail customers and then to the public.

The notified polymer is proposed to be used in domestic wash off shower cleaners by the general public and is expected to be disposed in sewage after its use. Some of the polymer might still remain on shower screens and is eventually expected to run into sewer with subsequent washes of the shower screen.

6. HUMAN HEALTH IMPLICATIONS**6.1. Exposure Assessment****6.1.1. Occupational Exposure****CATEGORY OF WORKERS**

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and warehouse	2-3	25
Process operator (formulation)	2-3	25
Quality control	1-2	4-5
Packaging	2-3	25
Waste management	1	40

EXPOSURE DETAILS*Transport and storage*

The primary work activity undertaken by transport and warehouse workers will include the handling, loading and off-loading of plastic containers containing the notified polymer in neat form and/or end-use products containing <5% of the notified polymer. Exposure of these workers will be limited to the unlikely event where the packaging is breached leading to discharge and from clean-up of spills. In such an event, a worker may be exposed through the dermal and accidental ocular contact. The notifier states that exposure will be minimised through the use of personal protective equipment (PPE).

Formulation of end products

During formulation dermal, ocular and inhalation exposure of workers to the notified polymer may occur during weighing and transfer stages, blending, sampling, quality control analysis and cleaning and maintenance of blending equipment. The notifier anticipates that typical practices in blending of cleaning products will include automated enclosed processes with good ventilation. The exposure will be further reduced through the use of PPE including protective clothing, impervious gloves, goggles, safety boots and respiratory protection if required.

Professional cleaners

Exposure to the notified polymer in end-use products (at < 5% concentration) may occur in work areas where the service provided involves the use of cleaning products in the cleaning industry. The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible. Such professionals may use some PPE to minimise repeated exposure. However, 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 cleaning products containing < 5% of the notified polymer will be available to public for domestic cleaning, particularly for showers. It is expected to be available in spray and pour bottles and applied in form of spray or by pouring onto the surface. Dermal and accidental ocular and inhalation exposure to the notified polymer may occur during application of the cleaning product. The exposure frequency and duration is expected to be low due to the expected infrequent use of the cleaning product.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix A.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Skin irritation (in vitro)	non-irritating
Eye irritation (in vitro)	non-irritating
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution

No information on toxicokinetics, metabolism and distribution was provided. The notified polymer is of high molecular weight (> 1,000 Da), expected to be charged and have low partition coefficient. Due to the size and the predicted physico-chemical properties the notified polymer is unlikely to cross biological membranes.

Acute toxicity

The notified polymer was found to be of low toxicity via the oral route in an animal acute toxicity study.

Irritation and sensitisation

The notified polymer was tested for skin and eye irritation potential using *in vitro* test methods. The skin irritation study predated the corresponding OECD test guideline, and there is no validated OECD test guideline for the *in vitro* eye irritation test. The notified polymer did not meet the criteria for classification for skin irritation and the cell viability of the test substance exposed tissue was very similar to the negative control. The notified polymer did not meet the criteria for classification for eye irritation. However, although stated to be non-irritating in the study report, the cell viability was markedly reduced (81.8% compared to 100% in control) when compared to the negative control suggesting there is a potential for some eye irritation effects.

No information on skin sensitisation potential of the notified polymer was provided.

Repeated dose toxicity

No information on repeated dose toxicity potential of the notified polymer was provided. Considering the high molecular weight of the notified polymer, it is not expected to be absorbed to cause systemic effects.

Mutagenicity/Genotoxicity

The notified polymer was non-mutagenic in an *in vitro* bacterial reverse mutation test.

Health hazard classification

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

6.3. Human Health Risk Characterisation

Based on the limited information, the notified polymer is not expected to be irritating to skin but some potential for eye irritation cannot be ruled out.

6.3.1. Occupational Health and Safety

Reformulation workers may come in contact with the notified polymer during reformulation, quality control and equipment cleaning and maintenance. The worker exposure is expected to be low due to the automated processes and the proposed use of PPE by the notifier. Based on the available information and the proposed control measures and use of PPE, the risk to workers is not considered to be unreasonable.

Professional cleaners may experience repeated exposure to the notified polymer during the use of the cleaning products containing < 5% of the notified polymer. These professionals may experience dermal and accidental ocular and inhalation exposure during application of the cleaning products containing < 5% of the notified polymer. Given the low concentration of the notified polymer in end-use products, likely use of PPE and the expected low hazard, the risk to professional workers associated with the use of products containing the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

Domestic cleaning products containing the notified polymer at < 5% concentration will be available to the public particularly for shower cleaning. The main route of exposure is expected to be dermal with some potential for accidental ocular or inhalation exposure.

Based on the available information, low concentration in end-use products (<5%) and infrequent use, the risk to the public from use of the notified polymer in cleaning 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 imported notified polymer will be reformulated in an enclosed system in Australia for use in domestic cleaning products. Accidental spills of the notified polymer during import, transport, reformulation or storage are expected to be adsorbed onto a suitable material and collected for disposal in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

The notified polymer will be used as a component of wash off shower cleaning products. Therefore, the release of the polymer from use will primarily be to sewers across Australia, and then to sewage treatment plants (STPs).

RELEASE OF CHEMICAL FROM DISPOSAL

Residues of the notified polymer in empty import and end-use containers are likely to either share the fate of the containers and be disposed of to landfill, or be released to the sewer system when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate

The notified polymer is not readily biodegradable based on the information from the notifier's SDS. However, the full study report was not provided. The notified polymer is not expected to significantly bioaccumulate in aquatic life based on its high molecular weight and surface activity.

Following the use as a component of wash off shower cleaning products, the majority of the notified polymer is expected to be released to sewers, and then to STPs. Based on its high molecular weight and cationic characteristics, the notified polymer is expected to be efficiently removed through adsorption of the cationic polymer to sludge or by flocculation at STPs (Boethling and Nabholz, 1997).

Sludge containing the notified polymer will be sent to landfill for disposal or to agricultural land for remediation. The notified polymer will bind to soil or sludge due to its cationic functions and is not expected to be mobile in the environment (Boethling and Nabholz, 1997). In landfill, soil, sludge and water, the notified polymer is expected to undergo slow degradation by biotic and abiotic processes, eventually forming water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

As the notified polymer will be used as a component of wash off shower cleaning products, the total import volume of the notified polymer is expected to be released to sewers during its use. It is also anticipated that such releases will occur over 365 days per annum into the Australian effluent volume. The notified polymer is a cationic polymer with molecular weight > 1,000 Da and therefore, 90% of the notified polymer is expected to be removed by partition to sludge or by flocculation at STPs (Boethling and Nabholz, 1997). The resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	3,000	kg/year
Proportion expected to be released to sewer	100	%
Annual quantity of chemical released to sewer	3,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	8.22	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24,168	million
Removal within STP	90%	
Daily effluent production:	4,834	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.17	µg/L
PEC - Ocean:	0.02	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m³). Using these assumptions, irrigation with a concentration of 0.17 µg/L may potentially result in a soil concentration of approximately 1.13 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 5.57 µg/kg and 11.3 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from the ecotoxicological investigation conducted on the notified polymer are summarised in the table below. Details of the study can be found in Appendix C.

Endpoint	Result	Assessment Conclusion
Algal Toxicity (96 h)	EC50 = 0.21 mg/L	Very toxic to alga

Under the *Globally Harmonised System of Classification and Labeling of Chemicals (GHS)* the notified polymer is expected to be very toxic to alga. Therefore, the notified polymer is formally classified as “Acute Category 1; Very toxic to aquatic life” under the GHS.

Based on the acute toxicity and lack of readily biodegradation, the notified polymer is formally classified as “Chronic Category 1; Very toxic to aquatic life with long lasting effects” under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated based on the acute endpoint for alga. A safety factor of 1000 was used given the acute endpoint for only one trophic level is available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga, 96h)	0.21	mg/L
Assessment Factor	1,000	
Mitigation Factor	1.00	
PNEC:	0.21	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.17	0.21	0.810
Q - Ocean	0.02	0.21	0.081

The risk quotient for discharge of effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on its maximum annual importation quantity. Although the notified polymer is likely to be persistent in the environmental it is not

expected to be bioaccumulative due to the cationicity and high molecular weight of the notified polymer. Therefore, on the basis of the PEC/PNEC ratio, the maximum annual importation volume and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 420 Acute Oral Toxicity - Fixed Dose Method (2001).
Species/Strain	Rat/RccHan TM ;WIST
Vehicle	Arachis oil BP
Remarks - Method	No significant deviations from the OECD test guideline.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	1 F	300	0/1
2	1 F	2,000	0/1
3	4 F	2,000	0/4

LD50	> 2,000 mg/kg bw
Signs of Toxicity	Hunched posture was noted in group 2 test animal
Effects in Organs	None reported
Remarks - Results	All the test animals survived the study. No abnormalities were found in necropsy and all the test animals showed expected weight gains.

CONCLUSION	The notified polymer is of low toxicity via the oral route.
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TEST FACILITY	Harlan (2010a)
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B.2. Irritation – skin (in vitro)

TEST SUBSTANCE	Notified polymer
METHOD	Method similar to OECD TG 439 In vitro Skin Irritation: Reconstructed Human <i>Epidermis</i> Test Method (2010)
Vehicle	None
Remarks - Method	The test was conducted before the adoption of the OECD test guideline. No significant deviations from the OECD test guideline were noted. The exposure period for test substance was 15 minutes and 10 µl of test substance was applied to the skin tissue. Conversion of 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide (MTT) to blue formazan salt was measured to quantify cell viability.

RESULTS

<i>Test material</i>	<i>Mean OD₅₇₀ of triplicate tissues ± SD</i>	<i>% Relative mean Viability ± SD</i>
<i>Negative control</i>	0.709 ± 0.008	100 ± 1.2*
<i>Test substance</i>	0.693 ± 0.015	97.8 ± 2.1
<i>Positive control</i>	0.060 ± 0.017	8.5 ± 2.4

OD = Optical Density, SD = Standard Deviation

* - normalised to 100%

Remarks - Results	No test substance mediated conversion of MTT was seen. The cell viability seen in the test substance treated tissue was greater than the viability required for classification (< 50%).
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CONCLUSION	The notified polymer was non-irritating to the skin under the conditions of the test.
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TEST FACILITY	Harlan (2010b)
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B.3. Irritation – eye (in vitro)

TEST SUBSTANCE	Notified polymer
METHOD	Determination of Ocular Irritation Potential Using the SkinEthic Reconstituted Human Corneal Epithelium Model
Vehicle	None
Remarks - Method	30 µL of test substance was applied to the tissues in triplicates. Following 10 minute exposure at 37°C, the tissues were rinsed with phosphate buffered saline medium and treated with MTT and incubated for approximately three hours. Following extraction, the optical densities were measured at 540nm. Two the three samples were used for measurement of MTT. Solution A (similar in composition to the cell maintenance medium) supplied with the assay kit was used as negative control and 1% w/v SDS was used as positive control.

RESULTS

<i>Test material</i>	<i>Mean OD₅₄₀ of duplicate tissues</i>	<i>Relative mean viability (%)</i>
<i>Negative control</i>	1.087	100*
<i>Test substance</i>	0.889	81.8
<i>Positive control</i>	0.469	43.1

OD = optical density

* - normalised to 100%

Remarks - Results	No test substance mediated conversion of MTT was seen. The cell viability seen in the test substance treated tissue was greater than the viability required for classification (< 60%).
CONCLUSION	The notified polymer was considered to be non-irritating to the eye by the study author(s) under the conditions of the test.
TEST FACILITY	Harlan (2010c)

B.4. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure and Pre incubation procedure
Species/Strain	<i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100 <i>E. coli</i> : WP2uvrA ⁻
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver
Concentration Range in	a) With metabolic activation: 1.5 - 5,000 µg/plate
Main Test	b) Without metabolic activation: 1.5 - 5,000 µg/plate
Vehicle	Sterile distilled water
Remarks - Method	No significant deviations from the OECD test guideline. The test substance was dissolved in sterile distilled water by mixing on a vortex and sonication for 5 minutes at 40°C on the day of each experiment. A preliminary toxicity test was conducted to determine the dose for main study. The number of revertant colonies was quantified in the preliminary toxicity test. In main study experiment 1 was conducted following plate incorporation procedure and experiment 2 was conducted following pre-incubation procedure. Experiment 2 without S9 fraction was repeated again for strains TA100, TA1535 and TA1537 using lower test substance concentrations due to the toxicity observed in main test.

RESULTS

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

Remarks - Results

All the positive controls induced marked increases in the frequency of revertant colonies confirming the activity of the S9-mix and the sensitivity of the test strains. The negative controls gave satisfactory results.

CONCLUSION

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

TEST FACILITY

Harlan (2010d)

APPENDIX B: ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Ecotoxicological Investigations

B.1.1. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 201 Freshwater Alga, Growth Inhibition Test. EC Council Regulation No 761/2009 C.3 Algal Inhibition Test. US EPA Draft Ecological Effects Test Guideline OPPTS 850.5400
Species	<i>Pseudokirchneriella subcapitata</i>
Exposure Period	96 hours
Concentration Range	Nominal: Control, 0.10, 1.0, 10, 100 and 1,000 mg/L
Auxiliary Solvent	No
Water Hardness	Not reported (the test used reverse osmosis purified deionized water)
Analytical Monitoring	Coulter® Multisizer Particle Counter
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

The test item was dissolved in culture medium to give a 1,000 mg/L stock solution from which a series of dilutions was made to give further stock solutions of 100, 10, 1.0 and 0.10 mg/L. An aliquot of each of the stock solutions was separately inoculated with algal suspension to give the required test concentrations of 0.10, 1.0, 10, 100 and 1,000 mg/L. The control group was maintained under identical conditions but not exposed to the test item.

RESULTS

<i>Ebc50</i> mg/L at 96 h	<i>Biomass</i>	<i>Growth</i>	
	<i>NOEC</i> mg/L at 96 h	<i>ErC50</i> mg/L at 96 h (95% confidence limits)	<i>NOEC</i> mg/L at 96 h
Not determined	Not determined	0.21 (0.16-0.28)	<0.10

Remarks - Results

The test was considered reliable as all validity criteria were satisfied. The results above were based on nominal concentrations of the test item. The results showed a significant effect on growth at all test concentrations employed. Visual inspection of the data indicated that the No Observed Effect Concentration (NOEC) was less than 0.10 mg/L. EC50 and NOEC were not determined for biomass.

All test and control culture were inspected microscopically at 96 hours. After 96 hours, there were no abnormalities detected in the control or test cultures at 0.10 and 1.0 mg/L, however clumped cells were observed to be present in the test cultures at 10 mg/L, and few intact cells were observed to be present in the test cultures at 100 and 1,000 mg/L.

CONCLUSION

The notified polymer is expected to be very toxic to alga

TEST FACILITY

Harlan (2012)

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