

File No: LTD/1733,
LTD/1734,
LTD/1735
and LTD/1736

September 2014

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

PUBLIC REPORT

LTD/1733: Polymer 1 in Detergent B
LTD/1734: Polymer 2 in Detergent B
LTD/1735: Polymer 3 in Detergent C
LTD/1736: Polymer 4 in Detergent C

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
LTD/1733, LTD/1734, LTD/1735 and LTD/1736	Kao Australia Pty Ltd	LTD/1733: Polymer 1 in Detergent B LTD/1734: Polymer 2 in Detergent B LTD/1735: Polymer 3 in Detergent C LTD/1736: Polymer 4 in Detergent C	ND*	LTD/1733: ≤ 6 tonnes per annum LTD/1734: ≤ 9 tonnes per annum LTD/1735: ≤ 5 tonnes per annum LTD/1736: < 1 tonnes per annum	Component of liquid laundry detergents

*Not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification

Based on the limited available information, the notified polymers are 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).

Human Health Risk Assessment

Under the conditions of the occupational settings described, the notified polymers are not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymers are 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 polymers are 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 polymers as introduced in laundry detergents:
 - Avoid skin or eye contact with the products.
 - Rinse off any skin or eye contamination with large quantity of water immediately.
 - Clean up spills promptly.
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymers as introduced in laundry detergents:
 - Impervious gloves, if dermal exposure may occur.

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

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

- If products and mixtures containing the notified polymers 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

- The notified polymers should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified polymers should be handled by 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 polymers are 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 polymers have a number-average molecular weight of less than 1000;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymers has changed from components of liquid laundry detergent, or is likely to change significantly;
 - the amount of polymers being introduced has increased, or is likely to increase, significantly;
 - the polymers have begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymers 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 (M)SDS of the products containing the notified polymers provided by the notifier were 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)

Kao Australia Pty Ltd (ABN: 059 054 708 299)
1A The Crescent
Kingsgrove NSW 2208

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 and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, additives/adjuvants and manufacture/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 properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

LTD/1733: Detergent B (product containing the notified polymer)
LTD/1734: Detergent B (product containing the notified polymer)
LTD/1735: Detergent C (product containing the notified polymer)
LTD/1736: Detergent C (product containing the notified polymer)

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference FTIR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 70%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)

None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Polymer in solution is colourless to amber liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Polymer in solution
Boiling Point	Not determined	Polymer in solution
Density	Not determined	-
Vapour Pressure	8×10^{-22} kPa at 25°C	Calculated based on an oligomer with

Water Solubility	Not determined	lower molecular weight The notified polymers are expected to be water dispersible based on the presence of hydrophilic functionality and its use in aqueous products
Hydrolysis as a Function of pH	Not determined	The notified polymers contain hydrolysable functionalities that are expected to slowly hydrolyse under environmental conditions (pH 4-9)
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to the interface between octanol and water based on their structure
Adsorption/Desorption	Not determined	Expected to have low mobility in soil based on its high molecular weight
Dissociation Constant	Not determined	Three of the notified polymers are salts and are expected to be ionised under environmental conditions (pH 4-9)
Flash Point	Not determined	-
Flammability	Not determined	-
Autoignition Temperature	Not determined	-
Explosive Properties	Not determined	Not expected to have explosive properties based on structure
Oxidising Properties	Not determined	Not expected to have oxidising properties based on structure

DISCUSSION OF PROPERTIES

Reactivity

The notified polymers are expected to be stable under normal conditions of use.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymers are 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 polymers will be imported at up to 8% total concentration in Detergent B and up to 5.5% total concentration in Detergent C. There will be no reformulation or repackaging in Australia. The concentration of the individual polymers in the detergents is as follows:

LTD/1733: 1-3%

LTD/1734: < 5%

LTD/1735: < 5%

LTD/1736: < 0.5%

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

Year	1	2	3	4	5
	Tonnes				
LTD/1733:	1-6	1-6	1-6	1-6	1-6
LTD/1734:	1-9	1-9	1-9	1-9	1-9
LTD/1735:	1-5	1-5	1-5	1-5	1-5
LTD/1736:	<1	<1	<1	<1	<1

PORT OF ENTRY

Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS

Kao Australia Pty Ltd

TRANSPORTATION AND PACKAGING

The liquid laundry detergents containing the notified polymers will be imported in 650 mL plastic bottles packaged in cardboard box shippers and shrink wrapped on pallets.

The products containing the notified polymers will be imported by sea freight and transported by truck to the notifier's warehouse for storage. The products will then be distributed by road throughout Australia to local retail outlets and commercial laundries.

USE

The notified polymers will be imported as components of finished liquid laundry detergents.

OPERATION DESCRIPTION

There will be no reformulation or repackaging of liquid laundry detergents containing the notified polymers in Australia.

End-use

Laundry workers and consumers will open the liquid laundry detergent containers (containing up to 8% of the notified polymers) and manually measure out the required volume of the products (typically 50 mL). The products will be measured using the cap of the container or into a plastic measuring/dispensing cup before adding to the washing machine. After the washing process the consumers will remove washed clothes from the machine. At this stage the notified polymers will be almost completely rinsed off from the clothes.

The liquid laundry detergents may also be used in hand-washing of clothes.

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 workers	2-3	24
Retail workers	8	200
Professional laundry workers	8-12	200

EXPOSURE DETAILS

Transport and storage

Transport, storage and retail workers will only be exposed to the notified polymers (at up to 8% total concentration in Detergent B and up to 5.5% total concentration in Detergent C) in the unlikely event of an accident. Retail workers are likely to be exposed if the liquid detergent packaging was damaged and in the course of cleaning up of spilled material. In these cases dermal and ocular exposure may occur.

End-use

Laundry workers may be exposed to the products (Detergent B and Detergent C) via dermal route containing up to 8% of the notified polymers during measuring and dispensing of the liquid laundry detergents. Accidental ocular exposure may also occur.

6.1.2. Public Exposure

The liquid laundry detergents containing up to 8% of the notified polymers will be available to the public through retail outlets. Exposure may result during measuring and dispensing of the products for automatic laundering processes and during manual laundering. The most likely route of exposure will be dermal; however, ocular exposure may also occur. Inhalation exposure is not expected. The use of PPE such as protective gloves is likely to be highly variable between consumers.

If hand-washing of clothes is carried out using the laundry detergent, there may be dermal exposure to the diluted detergent containing low levels of the notified polymers (< 0.01% total concentration).

The laundry detergent will be rinsed off from clothes at the end of the washing cycle. Trace quantities of residual polymers on clothes may remain, however the levels are expected to be very low.

6.2. Human Health Effects Assessment

The results from toxicological investigations were conducted on a product containing 50% of the notified polymer LTD/1733, the parent acid, and 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 (50% notified polymer)	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation (50% notified polymer)	slightly irritating
Rabbit, eye irritation (50% notified polymer)	slightly irritating
Mutagenicity – bacterial reverse mutation (50% notified polymer)	non mutagenic

Toxicokinetics, metabolism and distribution.

No toxicokinetic data on the notified polymers were submitted. Absorption through the skin and gastrointestinal tract is expected to be limited due to the molecular weight (> 1000 Da). The low vapour pressure (calculated based on an oligomer with smaller molecular weight) indicates that the notified polymers are not likely to be inhaled as a vapour.

Acute toxicity.

The notified polymer LTD/1733 at 50% concentration was found to be of low acute oral toxicity (> 2000 mg/kg bw) in the rat.

No dermal or inhalation acute toxicity studies were submitted.

Irritation and sensitisation.

The notified polymer LTD/1733 at 50% concentration was slightly irritating to the rabbit skin. Very slight erythema and oedema were observed at one hour after removal of dressing but not at later observations.

In an eye irritation study in rabbits on the notified polymer LTD/1733 at 50%, redness of the conjunctiva was observed, below the cut-off level for classification. Mild corneal opacity was also seen at 1 h, but had resolved by the 24 h observation. It is not known whether the eye irritation effects of the polymer at 100% would meet the criteria for classification.

No studies on skin sensitisation were submitted.

Mutagenicity/Genotoxicity.

The notified polymer LTD/1733 at 50% concentration was not mutagenic in a bacterial reverse mutation study.

Health hazard classification

Based on the limited available information, the notified polymer LTD/1733 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 studies in rabbits conducted on LTD/1733, the notified polymers have irritation potential, particularly to eyes. The severity of irritation is likely to be reduced by the relatively low concentration in the imported products (up to 8%). Dermal and ocular exposure to up to 8% of the notified polymers in Detergent B and up to 5.5% in Detergent C may occur during transport and handling of products at retail outlets if there is accidental spillage. Workers at end-use commercial laundry operations may also have incidental dermal or ocular exposure

to the notified polymers at 8% through splashes and spills. Inhalation exposure is not expected. The use of personal protective equipment (PPE) such as gloves would reduce the potential for exposure.

If safe work practices and PPE are used to reduce exposure, the risk to the health of workers from laundry products containing the notified polymers is not considered to be unreasonable.

6.3.2. Public Health

Limited toxicological data available on one of the notified polymers indicates that they have some irritation potential. The severity of irritation would be reduced by the relatively low concentration in the imported laundry detergents (up to 8%). Members of the public may come into incidental dermal or ocular contact with the laundry detergents, however it is expected that any splashes would be washed off immediately, if such exposures occur. Members of the public may also have dermal exposure to low concentrations of the polymers during hand-washing, however irritation is not expected at these dilutions.

Systemic exposure to the polymers would be limited by their molecular weight (> 1000) and low levels of low molecular weight species.

Overall the exposure of the public is expected to be low, and the risk to public health 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 polymers are not manufactured, reformulated or repackaged in Australia; therefore there will be no release to the environment from these activities. Environmental release during transport and storage may occur as a result of accidental spills (up to 1% of the total import volume). Spills are expected to be cleaned up by using an appropriate sorbent material and disposed of to landfill, or washed to sewers.

RELEASE OF CHEMICAL FROM USE

During use as a laundry detergent, approximately the entire volume of the notified polymers is expected to be released to sewers. Spills are expected to be cleaned up by using an appropriate sorbent material and disposed of to landfill, or washed to sewers. Residues of the notified polymers in the empty containers (up to 2%) are likely to be rinsed and will be added into the washing machine or released to sewer, or disposed of to landfill with the empty containers.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymers are expected to be released to sewer. A small amount of the notified polymers is likely to be disposed of to landfill via domestic waste when empty containers are disposed of or when unused laundry detergents are discarded.

7.1.2. Environmental Fate

No environmental fate data was submitted for notified polymers. The notified polymers have potential to slowly degrade in the aquatic environment under normal environmental conditions based on structural considerations.

The majority of the notified polymers are expected to be released to sewage treatment plants (STPs) via domestic wastewater. Based on their molecular weight no removal of the notified polymers from STP effluent is anticipated (Boethling & Nahbolz, 1997) and the notified polymers are expected to remain in the water column. Notified polymers reaching surface waters via treated STP effluent are expected to disperse and degrade. Based on their high molecular weight, the notified polymers are not expected to be bioaccumulative. A minor amount of notified polymers, as residues in empty containers, are expected to be disposed of to landfill or recycling facilities. The notified polymers are expected to degrade through biotic and abiotic processes to form water, oxides of carbon and nitrogen and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the Predicted Environmental Concentration (PEC) is summarised in the table below. Based on the reported use in laundry detergents, it is assumed that 100% of the total import volume of the notified polymers is expected to be released to the sewer. The release is assumed to be nationwide over 365 days per year. It is assumed that none of the notified polymers would be removed from STP effluents.

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>		
Total Annual Import/Manufactured Volume	21,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	21,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	57.53	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	12.72	µg/L
PEC - Ocean:	1.27	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified polymers in this volume are assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 12.72 µg/L may potentially result in a soil concentration of approximately 0.08 mg/kg. Assuming accumulation of the notified polymers in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymers in the applied soil in 5 and 10 years may be approximately 0.42 mg/kg and 0.85 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified polymers. The notified polymers are anionic polymers to which algae is expected to be the most sensitive species. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone, which applies to the notified polymer. The result from an ecotoxicological investigation conducted on a similar polyanionic polymer was available in Boethling & Nabholz (1997), and is presented in the table below. The endpoint presented below is likely to reflect the worst case ecotoxicity of the notified polymers. Furthermore, the indirect toxicity to algae is likely to be further reduced due to the presence of calcium ions in the aquatic compartment which will bind to the functional groups the notified polymers.

Endpoint	Result	Assessment Conclusion
Algal Toxicity (96 h)	EC50 = 3.13 mg/L	Potentially toxic to algae

The notified polymers may pose a hazard to algae by indirect toxicity. Whilst use of representative analogue data is considered reliable to provide general indications of the likely environmental effects of the notified polymers, the data is not considered adequate to formally classify the acute and long term hazard of the notified polymers 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

The predicted no-effect concentration (PNEC) was calculated from the acute toxicity data (algae). An assessment factor of 100 was used as algae is known to be the most sensitive taxa (out of the three standard trophic levels, i.e. fish, invertebrates and algae) to this class of chemicals.

<i>Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment</i>		
EC50 (Alga).	3.13	mg/L
Assessment Factor	100	
PNEC:	31.3	µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotients (RQ) (PEC/PNEC) have been calculated for the aquatic compartment:

<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC µg/L</i>	<i>Q</i>
Q - River:	12.72	31.3	0.41
Q - Ocean:	1.27	31.3	0.04

The above risk quotients are upper limits as they have been calculated using a conservative algal toxicity. The notified polymers are likely to reach surface waters, however toxicity is expected to be mitigated by prevailing water hardness. The notified polymers are not expected to be bioaccumulative. As the risk quotient is < 1 for the worst case effluent discharge scenario, the notified polymers are not expected to pose an unreasonable risk to the environment on the basis of their assessed use pattern and maximum annual importation volume.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS**B.1. Acute toxicity – oral**

TEST SUBSTANCE	Notified polymer LTD/1733 (1:1 ratio of notified polymer and water)
METHOD	EC Council Regulation No 440/2008 B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/Hsd:Sprague-Dawley(CD)
Vehicle	None
Remarks - Method	No control animals were included in the study.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5F/5M	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	Piloerection was observed in all animals within four minutes of dosing, persisting through to day 5 in all animals. There were no other clinical signs.
Effects in Organs	There were no macroscopic abnormalities observed during necropsy (day 15).
Remarks - Results	Recovery from piloerection was complete by day 6. All animals achieved satisfactory bodyweight gains throughout the study.

CONCLUSION The test substance is of low toxicity via the oral route.

TEST FACILITY Huntingdon (1996a)

B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer LTD/1733 (1:1 ratio of notified polymer and water)
METHOD	EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3M
Vehicle	None
Observation Period	4 days
Type of Dressing	Semi-occlusive.

RESULTS

Remarks – Results	Very slight erythema and oedema (both barely perceptible) were observed 60 minutes after removal of dressing. No signs of erythema and oedema were observed at days 24, 48 and 72 hours after exposure.
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CONCLUSION The test substance is slightly irritating to the skin.

TEST FACILITY Huntingdon (1996d)

B.3. Irritation – eye

TEST SUBSTANCE	Notified polymer LTD/1733 (1:1 ratio of notified polymer and water)
METHOD	EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White

Number of Animals	3M
Observation Period	7 days
Remarks - Method	A pilot animal was tested in advance for severe reaction. Conjunctival discharge was not reported.

RESULTS

Lesion	Mean Score*			Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	Animal No.	1	2	3		
<i>Conjunctiva: redness</i>	1	1.7	2	2	Less than day 7	0
<i>Conjunctiva: chemosis</i>	0	0	0	0	n/a	0
<i>Conjunctiva: discharge</i>	n/a	n/a	n/a	n/a	n/a	0
<i>Corneal opacity</i>	0	0	0	0	n/a	0
<i>Iridial inflammation</i>	0	0	0	0	n/a	0

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

Remarks - Results	At the 1h observation only, corneal opacity was seen in one animal and dulling of the cornea in the other two animals. These effects were not seen at subsequent observations. The last day when effects were seen was day 4 (no recorded observations were made at days 5 and 6).
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CONCLUSION	The test substance is slightly irritating to the eye.
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TEST FACILITY	Huntingdon (1996c)
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B.4. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer LTD/1733 (1:1 ratio of notified polymer and water)
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 <i>S. typhimurium</i> : TA1535, TA1537, TA98 and TA100 <i>E. coli</i> : WP2uvrA
Species/Strain	
Metabolic Activation System	Aroclor 1254 induced rat liver S9
Concentration Range in Main Test	a) With metabolic activation: 0.0, 312.5, 625, 1250, 2500 and 5000 µg/plate b) Without metabolic activation: 0.0, 312.5, 625, 1250, 2500 and 5000 µg/plate
Vehicle	Water
Remarks - Method	Doses for the main tests were chosen on the basis of a preliminary toxicity test.

RESULTS

Metabolic Activation	Test Substance Concentration (µg/plate) Resulting in:			
	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect
<i>Absent</i>				
Test 1	≥5000	≥2500	-	Negative
Test 2	-	>5000	-	Negative
<i>Present</i>				
Test 1	>5000	>5000*	-	Negative
Test 2	-	≥2500	-	Negative

*However, toxicity was seen at all concentrations in TA1537

Remarks - Results	Precipitation was not reported. The positive controls showed large increases in revertants, confirming the validity of the test system.
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CONCLUSION	The test substance was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Huntingdon (1996b)

BIBLIOGRAPHY

- Boethling RS & Nabholz JV (1997) Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton JD & Sutcliffe R, ed. Ecological Assessment of Polymers; Strategies for product stewardship and regulatory programs. New York, Van Nostrand Reinhold, pp 187–234.
- Huntingdon (1996a) [Notified polymer LTD/1733] Acute oral toxicity to the rat (Study No.: NSK 75/961606/AC, July, 1996). Cambridgeshire, England, Huntingdon Life Sciences (Unpublished report submitted by the notifier).
- Huntingdon (1996b) [Notified polymer LTD/1733] Bacterial mutation assay (Study No.: NSK 69/960042, February, 1996). Cambridgeshire, England, Huntingdon Life Sciences (Unpublished report submitted by the notifier).
- Huntingdon (1996c) [Notified polymer LTD/1733] Eye irritation to the rabbit (Study No.: NSK 76/961647/SE, July, 1996). Cambridgeshire, England, Huntingdon Life Sciences (Unpublished report submitted by the notifier).
- Huntingdon (1996d) [Notified polymer LTD/1733] Skin irritation to the rabbit (Study No.: NSK 67/960112/SE, July, 1996). Cambridgeshire, England, Huntingdon Life Sciences (Unpublished report submitted by the notifier).
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- 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>.