File No: LTD/1641

December 2012

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Keropur DP 5100

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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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/1641	BASF Australia Ltd	Polymer in Keropur DP 5100	ND*	≤ 75 tonnes per annum	An additive in fuel

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the limited toxicity data provided, the notified polymer cannot be classified 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 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 assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure during transfers of the notified polymer as introduced in the product Keropur DP 5100:
  - Closed and automated processes where possible
  - Adequate local exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced in the product Keropur DP 5100:
  - Do not generate aerosols during transfer and mixing
  - Prevent from direct skin/eye contact with the product

- 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 during transfers of the notified polymer as introduced in the product Keropur DP 5100:
  - Protective clothing
  - Chemical glasses
  - Impervious gloves
  - Respirators if inhalation of the vapour or aerosols of the product is expected

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

Disposal

- The notified polymer should be disposed of to landfill.
- The notified polymer in fuel should be disposed of in accordance with local regulations for recycling, re-use or recovery of calorific content.

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;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from an additive in fuel, 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 (M)SDS of the product containing the notified polymer provided by the notifier was 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)
BASF Australia Ltd. (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place
Southbank, VIC 3006

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 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, residual monomers, impurities, additives/adjuvants, use details, import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: melting point/boiling point, vapour pressure, hydrolysis as a function of pH, partition co-efficient, adsorption/desorption, Dissociation constant, flammability, autoignition temperature, explosive properties, flash point, oxidising properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME
Keropur DP 5100 (product containing the notified polymer)

MOLECULAR WEIGHT
> 1,000 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 viscous liquid (product containing the notified polymer)

Property	Value	Data Source/Justification
Freezing Point	< -20 °C	Provided by the notifier
Boiling Point	179 - 214 °C at 101.3 kPa	Provided by the notifier
Density	936 kg/m^3 at 20 °C	Measured
Vapour Pressure	Not determined	Would be limited by the high molecular weight of the polymer, however significant levels of low molecular weight species are present.
Water Solubility	< 0.5% extractability	Measured
Hydrolysis as a Function of pH	Stable at 40 °C for 14 days at pH 4 - 9	Measured. Not expected to be significantly hydrolysed under environmental conditions (pH 4 - 9)
Partition Coefficient (n-octanol/water)	log Pow ≥ 4.5 at 20 °C	Estimated
Surface Tension	70 mN/m at 20 °C	Measured
Adsorption/Desorption	Not determined	Not likely to be mobile in soils based on molecular weight and potential cationic functionality.
Dissociation Constant	Not determined	Contains potentially cationic functionality with a typical pKa ~ 10 and is expected to ionise under environmental conditions (pH 4 - 9)

Flash Point	Not determined	Imported in flammable solvent
Autoignition Temperature	449 - 510 °C	Provided by the notifier
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties.

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

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

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

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as a component of a formulated product at concentrations 5 - 10%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 50	< 50	< 50	< 100	< 100

PORT OF ENTRY
Melbourne, Sydney, Brisbane, Perth, Adelaide and Hobart

IDENTITY OF MANUFACTURER/RECIPIENTS
BASF Australia Ltd

TRANSPORTATION AND PACKAGING
Formulated products containing the notified polymer at <10% will be imported into Australia by ship in packages < 1 L, 200 L, 1,000 L, intermediate bulk containers and in bulk shipments, and will be transported from the dockside to warehouses or customer sites for storage. The notified polymer may also be introduced as an ingredient in fuel.

USE
The notified polymer is an additive in diesel fuel for automotive engines.

OPERATION DESCRIPTION
The formulated products containing the notified polymer at < 10% will be stored in approved chemical warehouses and logistic facilities until further use. The products will be added into the fuel matrix in contained industrial facilities. The reformulated fuel containing the notified polymer at < 0.03% will be distributed to retail fuel outlets for commercial and consumer uses.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage of formulated products (3 - 10 workers)	6 - 8	12 - 15

Blender (1 - 5 workers)	6 - 8	125 - 225
Quality assurance analysis (1 - 2 workers)	6 - 8	125 - 225
Transport and storage of the fuel (1 -10 workers)	6 - 8	125 - 225

EXPOSURE DETAILS

Transport and storage of products containing the notified polymer are not expected to result in worker exposure under normal conditions, unless a spill occurs.

Workers transferring bulk shipments of the products, analysing the products, blending the products with fuel have potential for dermal, ocular exposure to the notified polymer at concentration < 10%. The notified polymer is not expected to be highly volatile, however the potential for inhalation exposure cannot be ruled out, as the polymer contains low molecular weight species. Inhalation exposure could also occur if aerosols were generated during processing. However the transfer of the additive product into fuel is carried out in contained facilities, with controls in place to address the flammability and toxicity of other components.

Transport storage workers and end-users of the fuel containing the notified polymer may have potential for dermal, ocular and inhalation exposure to the polymer at concentration < 0.03%.

6.1.2. Public Exposure

As the fuel containing the notified polymer will be distributed to retail fuel outlets for consumer use, the public may have potential for incidental dermal or ocular exposure to the notified polymer at concentration < 0.03% during refuelling processes. Due to the relatively enclosed nature of this process, inhalation exposure is not expected.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on a 50% solution of he notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
EpiDerm reconstructed human skin tissue - in vitro skin corrosion/irritation	No evidence of skin corrosion/irritation
Bovine cornea - in vitro eye corrosion/severe irritation	No evidence of eye corrosion /serious eye damage
EpiOcular reconstructed human cornea - in vitro eye irritation	No evidence of eye irritation
Mouse, skin sensitisation – Local lymph node assay (LLNA)	No evidence of skin sensitisation

Toxicokinetics, metabolism and distribution.

The number average molecular weight (Mn) of the notified polymer is above 1,000 Da. Polymers of high molecular weight do not readily cross the skin or other biological membranes. However, significant amounts of low molecular weight species (< 1,000) are present.

Acute toxicity.

The acute oral toxicity of a 50% solution the notified polymer in rats was low. No data on acute dermal and inhalation toxicity were available.

Irritation and sensitisation.

The notified polymer contains a structural alert for corrosion. An in vitro Epiderm test on a 50% solution of the notified polymer using reconstructed tissue did not show evidence of skin corrosion or irritation. Two in vitro studies (BCOP and EpiOcular) on the 50% solution did not show evidence of corrosion or severe irritation to the eye under the conditions of the studies. No in vivo animal study reports on skin and eye irritation were provided.

The notified polymer contains structural alerts for sensitisation. A Local Lymph Node Assay (LLNA) in mice on a 50% solution of the notified polymer did not show evidence of skin sensitisation. However the study was carried out at low concentrations (up to 5% of the solution, equivalent to 2.5% of the notified polymer) and the potential for skin sensitisation at higher concentrations cannot be ruled out.

Health hazard classification
Based on the limited toxicity data provided, the notified polymer cannot be classified 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
The notified polymer contains structural alerts for corrosion and sensitisation. Limited data on the toxicity of the notified polymer were available, indicating a 50% solution has low acute oral toxicity and low potential for skin and eye irritation. Skin sensitisation potential was tested only at low concentrations and the negative results in this study do not rule out the potential for sensitisation at higher concentrations.

Workers with the highest potential for exposure are operators and laboratory staff handling the product containing the notified polymer at up to 10%. This will be done in contained facilities with precautions in place, such as engineering controls and personal protective equipment (PPE), to minimise exposure to other hazardous components of the product. Once incorporated into fuel, potential exposure is much reduced, as the concentration of the notified polymer in fuel is low (< 0.03%). The notified polymer is expected to be combusted as part of the diesel fuel and will not be available for further exposure.

Based on the available information on toxicity and the occupational use scenarios and controls, the notified polymer is not expected to pose an unreasonable risk to workers.

6.3.2. Public Health
Public consumers of the fuel containing the notified polymer may have the potential for incidental dermal and ocular exposure to the polymer at low concentrations (< 0.03%) when refuelling. The notified polymer is expected to be combusted as part of the diesel fuel and will not be available for further exposure.

Based on the available information on toxicity and the expected low exposure of the public, the notified polymer is not expected to pose an unreasonable risk to the public.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will be manufactured and packaged into import and end-use containers overseas. There will be no environmental release of the polymer during these stages of the notified polymer's lifecycle.

RELEASE OF CHEMICAL FROM USE
The notified polymer will be imported as a formulation in 1 L cans, 200 L drums or 1,000 L containers, and possibly in bulk. Addition of the imported product to fuel will be automated and the fuel will be pumped directly into automotive fuel tanks. Environmental release is therefore expected to be limited to rare occasions of accidental spillage during transport and use. If spillage occurs, the notified polymer is expected to be contained and absorbed using an absorbent material and disposed of according to Local/State/Territory regulations, most likely to landfill. The majority of the notified polymer is expected to be thermally decomposed during use as fuel additive and its decomposition products released to the atmosphere.

RELEASE OF CHEMICAL FROM DISPOSAL
Empty containers containing the residue of the notified polymer (< 0.05% of the total import volume) are expected to be recycled by accredited waste management companies or disposed of according to local regulations. Some fuel or residues may be disposed of to landfill.

7.1.2. Environmental Fate
No environmental fate data were submitted. The majority of the notified polymer will be thermally decomposed during use and is expected to form water and oxides of carbon and nitrogen. The notified polymer is not likely to be readily biodegradable. It is also expected to have limited release to the aquatic environment based on the assessed use pattern. Notified polymer released to soil through leaks and spills, or released to landfill as residues

in empty containers, is expected to associate strongly with organic matter. It is expected to remain *in situ* based on its low water solubility, and potential high affinity for organic phases with an expected high n-octanol/water partition coefficient (log $P_{ow} \geq 4.5$) and likely high adsorption/desorption coefficient. The notified polymer and its transformation products are expected to degrade via biotic and abiotic processes to form simple organic compounds, water and oxides of carbon and nitrogen.

The notified polymer may bioaccumulate based on its low water solubility and high n-octanol/water partition coefficient (P_{ow}). The notified polymer's high molecular weight, combined with limited aquatic exposure, suggests that it has a low potential for bioaccumulation.

7.1.3. Predicted Environmental Concentration (PEC)

Exposure to the aquatic compartment is not expected during the use and disposal of the notified chemical. It is therefore not possible to calculate a predicted environmental concentration (PEC).

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer using a water accommodated fraction (WAF) are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Acute		
Daphnia Toxicity	EL50 > 100 mg/L	Not harmful to aquatic invertebrates up to its limit of solubility

The notified polymer is not expected to be acutely harmful to aquatic invertebrates up to the level of its solubility. Therefore, the notified polymer is not formally classified for acute or long-term hazard under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

Given the low water solubility and low potential for release of the notified polymer to the aquatic environment, the calculation of the PNEC is not considered necessary.

7.3. Environmental Risk Assessment

The notified polymer is expected to have limited release to the aquatic environment based on its assessed use pattern. The notified polymer has the potential to persist in the aquatic compartments however it has low toxicity to aquatic organisms and is not expected to bioaccumulate based on its high molecular weight. On the basis of the limited aquatic exposure, the notified polymer is not expected to pose an unreasonable risk to the environment for the assessed use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Density	936 kg/m^3 at 20 °C
Method	OECD TG 109 Density of Liquids and Solids.
Remarks	The density was measured by the pycnometer method using water as displacement liquid.
Test Facility	BASF (2012)

Water Solubility	< 0.5% extractability at 20 °C
Method	OECD TG 105 Water Solubility.
Remarks	Flask Method. The test substance is a mixture of constituents; therefore solubility in water is not constant. Solubility increased with the mass of the test substance. Results depended on the mass of the test substance and volume of water used. The test substance was soluble to about 5 mg/L (1 g test substance/L water) and 29 mg/L (10 g test substance/L water).
Test Facility	BASF (2012)

Partition Coefficient (n-octanol/water)	log Pow ≥ 4.5 at 20 °C
Method	Estimated from single solubilities in water and n-octanol.
Remarks	The test substance completely dissolved in n-octanol at the concentrations tested. The n-octanol solubility is ≥ 900 g/L. Using the water solubilities of 5 mg/L and 29 mg/L, log Pow ≥ 5.3 and ≥ 4.5 respectively.
Test Facility	BASF (2012)

Surface Tension	70 mN/m at 20 °C
Method	OECD TG 115 Surface Tension of Aqueous Solutions.
Remarks	Concentration: About 0.25 g of the test substance was treated with ultrasound in 250 ml water. The test substance was not completely dissolved and the residue was filtered off. A mixture of 90 ml filtered solution and 10 ml water (90% saturation concentration of the test substance) was used.
Test Facility	BASF (2012)

Stability Testing	Stable at pH 4, 7 and 9 at 40 °C for 14 days Stable at pH 1.2 at 40 °C for 24 hours
Method	Polymer Test Guideline of the Korean National Institute of Environmental Research (NIER)
Remarks	The test item is stable at environmental pH 4, 7 and 9 at 40 °C for 14 days and stable at pH 1.2 at 40 °C for 24 hours.
Test Facility	BASF (2012)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method EC Council Regulation No 440/2008 B.1 Acute Toxicity (Oral)
Species/Strain	Rat / Wistar Crl:WI (Han)
Vehicle	Olive oil (no vehicle for high dose Groups 2 and 3)
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3F	500	0/3
2	3F	2,000	0/3
3	3F	2,000	0/3

LD50	> 2,000 mg/kg bw
Signs of Toxicity	None observed during the study
Effects in Organs	None observed during the study
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	Bioassay (2011)

B.2. Corrosion/Irritation – skin

TEST SUBSTANCE Notified polymer

METHOD
OECD TG 431 In vitro Skin Corrosion - Human Skin Model Test; and
OECD TG 439 In vitro Skin Irritation - Reconstructed Human Epidermis Test Method
EC Council Regulation No 440/2008 B.40 BIS. In vitro Skin Corrosion - Human Skin Model Test.
EpiDerm™ Reconstructed Human Epidermis Model

Vehicle None

Remarks - Method Both skin irritation and skin corrosion tests were conducted.

For the skin corrosion test, the test substance (50 µL) was applied to the tissues in duplicate. Following exposure periods of 3 minutes (room temperature; test 1) and 1 hour (37 °C; test 2), the tissues were rinsed, treated with MTT [3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolim bromide; 1.0 mg/mL] and then incubated at 37 °C for 3 hours.

For the skin irritation test, the test substance (30 µL) was applied to the tissues in triplicate. Following an exposure period of 25 minutes at room temperature and then 35 minutes at 37 °C, the tissues were rinsed and then incubated in fresh medium at 37 °C for ~24 hours. The tissues were then transferred again to fresh medium and incubated at 37 °C for ~18 hours. The tissues were then treated with MTT and incubated at 37 °C for 3 hours. Following extraction, the optical densities were determined (570 nm).

The study authors noted that a preliminary test had been conducted, which indicated that the test substance does not directly reduce MTT.

Positive and negative controls were run in parallel with the test substance:

- Negative control (NC): water (corrosion test)
  PBS (irritation test)
- Positive control (PC): potassium hydroxide (8M, corrosion test)
  sodium dodecyl sulphate (5%, irritation test)

RESULTS

Corrosion test

Test material	*Test 1 (3 minute exposure period)*		*Test 2 (1 hour exposure period)*	
	Mean OD_{570} of duplicate tissues	*Relative mean viability (%)*	*Mean OD_{570} of duplicate tissues*	*Relative mean viability (%)*
Negative control	1.869	100	1.788	100
Test substance	1.898	102	1.924	108
Positive control	0.477	26	0.127	7

OD = optical density

Irritation test

Test material	*Mean OD_{570} of triplicate tissues*	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	1.900	100	2.40
Test substance	1.917	101	7.18
Positive control	0.148	8	0.59

OD = optical density; SD = standard deviation

Remarks - Results

The study authors noted that the test substance was observed on the tissues after washing. However, this was not considered to interfere with the MTT assay based on the results of the preliminary study.

The positive and negative controls gave satisfactory results, confirming the validities of the test systems.

CONCLUSION

The notified polymer was non-corrosive and non-irritating to the skin under the conditions of the tests.

TEST FACILITY

BASF (2011a)

B.3. Corrosion/Severe Irritation – eye

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants

Vehicle

None

Remarks - Method

No significant protocol deviations.

Water was used as a negative control and sodium hydroxide (1%) was used as a positive control in the study.

RESULTS

Test material	*Mean opacities of triplicate tissues (SD)*	*Mean permeabilities of triplicate tissues (SD)*	*IVIS (SD)*
Vehicle control	2.7 (3.6)	-0.001 (0.004)	2.7 (3.7)
Test substance	-2.1* (2.5)	-0.003* (0.003)	-2.1 (2.5)
Positive control	106.5* (14.7)	2.386* (0.189)	142.3 (17.5)

SD = Standard deviation; IVIS = in vitro irritancy score
*Corrected for background values

Remarks - Results

The controls gave satisfactory results confirming the validity of the test system.

CONCLUSION The notified polymer was not corrosive or a severe eye irritant under the conditions of the test.

TEST FACILITY BASF (2011b)

B.4. Irritation – eye

TEST SUBSTANCE Notified polymer

METHOD Determination of Ocular Irritation Potential Using the EpiOcular™ Reconstructed Human Corneal Epithelium Model

Vehicle None

Remarks - Method The test substance (50 µL) was applied to the tissues in duplicate. Following a 30 minute exposure period at ~37 °C, the tissues were rinsed and incubated at ~37 °C in fresh medium for 2 hours. The tissues were then treated with MTT and incubated at ~37 °C for 3 hours. Following extraction, the optical densities were determined (570 nm).

The study authors indicated that a preliminary test had been conducted, which indicated that the test substance does not directly reduce MTT.

The test substance was considered by the study authors to be an irritant if the relative mean tissue viability was ≤50%.

Positive and negative controls were run in parallel with the test substance:

- Negative control (NC): water
- Positive control (PC): methyl acetate (> 98%)

RESULTS -

Test material	*Mean OD_{570} of duplicate tissues*	*Relative mean viability (%)*
Negative control	1.351	100
Test substance	1.355	100
Positive control	0.272	20

OD = optical density

CONCLUSION The test substance was considered to be non-irritating to the eye under the conditions of the test.

TEST FACILITY BASF (2011c)

B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified polymer

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)

Species/Strain Mouse/CBA/CaOlaHsd

Vehicle 1,2-Propanediol (propylene glycol)

Remarks - Method The highest concentration tested was noted by the study authors to be the highest concentration that could be technically used, whilst avoiding systemic toxicity and excessive local irritation as determined based on preliminary experiments.

Positive control: 25% α-Hexyl cinnamaldehyde in acetone:olive oil (4:1).

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	171.6	1
1	60.7	0.34
2.5	134.7	0.78
5	293.3	1.71
Positive Control		
0	118.0	1
25	1287.5	10.91

Remarks - Results	One animal in the vehicle control group was accidentally treated with dimethylformamide instead of propylene glycol on the second application. This was not considered by the study authors to impact on the validity of the study. The proliferative response for this animal was not excluded from the results of the vehicle control group. A dose related response to the test substance was observed in the test groups, however, at the tested concentrations, the stimulation indices were < 3.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer under the conditions of the test.
TEST FACILITY	Harlan (2011)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test – Static. EC Council Regulation No 440/2008 C.2 Acute Toxicity for Daphnia – Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	160 - 180 mg $CaCO_3$/L
Analytical Monitoring	Total organic carbon analysis (TOC) was used to determine the concentration of test substance in solution at the beginning and end of the limit test.
Remarks - Method	A limit test was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. A range-finding test determined there were no observed effects at concentrations below the nominal concentrations used (1, 10 and 100 mg/L nominal loading rates). A siphoned water accommodated fraction (WAF) was used due to the test substances low water solubility. Water and the test substance were stirred at approximately 1,100 rpm for 72 hours. The solution was allowed to separate for 2 hours. The WAF was taken from the middle of the homogenous aqueous phase. The test organisms were exposed to the aqueous phase which may contain dissolved test material or leachates of the test material.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	3.43*	4 × 5	0	0
100	3.73*	4 × 5	0	0

*The concentrations appear to be background levels of organic carbon

EL50	> 100 mg/L (WAF) at 48 hours
NOEL	= 100 mg/L (WAF) at 48 hours
Remarks - Results	All relevant test validity criteria were met. No immobilisation or adverse behaviour was observed.
CONCLUSION	The notified polymer is not harmful to aquatic invertebrates up to the limit of its water solubility.
TEST FACILITY	Dr. U. NOACK (2012)

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