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August 2012

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Lutensit Z 96-70%

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 SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1609	BASF	Polymer in	ND*	≤ 10 tonnes per	Additive for use in
	Australia Ltd	Lutensit Z 96-70%		annum	laundry cleaning products

^{*}ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As no toxicity data were 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 PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

• 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.

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

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

Disposal

• The notified polymer should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

Secondary Notification

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

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

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a surfactant for use in laundry cleaning products, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 10 tonnes per annum, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physico-chemical properties.

Previous Notification in Australia by Applicant(s) None

NOTIFICATION IN OTHER COUNTRIES Canada (2003) China (2002) USA (2002)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Lutensit Z 96-70% (contains 70% notified polymer)

MOLECULAR WEIGHT Mn > 1,000 Da

ANALYTICAL DATA
Reference GPC spectrum was provided.

3. COMPOSITION

Degree of Purity > 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellow to brown liquid*

Property	Value	Data Source/Justification	
Melting Point/Freezing Point	Not determined	Introduced as an aqueous solution.	
Boiling Point	Not determined	Introduced as an aqueous solution.	
Density	$\sim 1100 \text{ kg/m}^3 \text{ at } 20 ^{\circ}\text{C}$	MSDS	
Vapour Pressure	Not determined	Based on high molecular weight vapour pressure is expected to be low.	
Water Solubility	Not determined	Expected to be water soluble based on its predominately hydrophilic chemical structure.	
Hydrolysis as a Function of pH	Not determined	The end groups of the notified polymer are expected to hydrolyse in the environment pH range of 4 – 9 based on the provided data, whereas the backbone is expected to be stable.	
Partition Coefficient (n-octanol/water)	Not determined	A low partition coefficient is expected based on its predominately hydrophilic chemical structure.	
Adsorption/Desorption	Not determined	May adsorb to soil or sediment due to the presence of cationic functional groups.	
Dissociation Constant	Not determined	The notified polymer is a salt and will be ionised under environmental conditions.	
Particle Size	Not determined	Introduced as an aqueous solution.	
Flash Point	Not determined	Introduced as an aqueous solution.	
Flammability	Not determined	Introduced as an aqueous solution.	
Autoignition Temperature	Not determined	Introduced as an aqueous solution.	
Explosive Properties	Not predicted to explode	Contains no functional groups that would imply explosive properties.	
Oxidising Properties	Not predicted to oxidise	Contains no functional groups that would imply oxidising properties.	

^{*}Aqueous solution containing 70% notified polymer

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 an aqueous solution at 70% concentration.

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

Year	1	2	3	4	5
Tonnes	1-10	1-10	1-10	1-10	1-10

PORT OF ENTRY Sydney

TRANSPORTATION AND PACKAGING

The notified polymer will be imported as an aqueous solution at 70% concentration in 1000L intermediate bulk containers. The bulk containers will be transported by road from the wharf to the contracted warehouse for storage and then distributed to reformulation sites. The finished liquid laundry detergent products (containing the notified polymer at < 3% concentration) will be packaged in various retail sizes (typically sizes vary from 475 mL to 5 L plastic packs) for distribution to retail outlets.

USE

Additive for use in laundry cleaning products.

OPERATION DESCRIPTION

At the formulation site, the intermediate bulk containers containing the notified polymer at $\sim 70\%$ will be connected by a hose to a delivery pump and the required amount pumped into a dipper or bucket. The contents of the dipper or bucket would then be poured into a blending vessel containing the other ingredients of the liquid laundry detergent. When blended, the batch will be sampled for QC and, once approval is received, formulated laundry products would be packaged for end use and transported by road to retail stores where they will be handled by storage and retail store personnel.

The formulated liquid detergent products containing the notified polymer at < 3% concentration may be used by commercial laundry workers and the public.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	Number	Exposure Duration (hours/day)	Exposure Frequency (days/year)
Transport and warehousing	1-10	2	< 5
Process workers/operators	1-5	4	50-60
Laboratory technicians/ maintenance workers	1-5	4	50-60
Transport and storage workers/ Retail workers	2000	5-8	200
Commercial laundry workers	5000	5-8	200

EXPOSURE DETAILS

Transport and Warehousing

During transportation, warehousing, and distribution, exposure to the notified polymer is not expected, except in the unlikely event of an accident where the packaging is damaged.

Reformulation

Dermal and possible ocular exposure to the notified polymer at concentrations up to 70% may occur when connecting and disconnecting transfer lines. Negligible exposure to the notified polymer is expected at other times during the reformulation process as blending and packaging will occur in enclosed systems and will be fully automated. Workers involved in the reformulation process are expected to wear impermeable gloves, eye protection and protective clothing to minimise exposure.

Based on the high molecular weight of the notified polymer and expected low vapour pressure, inhalation exposure is unlikely to occur. In addition, blending and packaging facilities are expected to be well ventilated and generally will also use local exhaust ventilation.

Use - Professional Laundry Workers

Laundry workers may be exposed to the finished products containing up to 3% of the notified polymer. The exposure may result during measuring and dispensing of the laundry product. The most likely route of exposure will be dermal. It is recommended that workers wear gloves during the dispensing operations.

6.1.2. Public Exposure

The public may be exposed to the finished products containing up to 3% of the notified polymer. The exposure may result during measuring and dispensing of the laundry product. The most likely route of exposure will be dermal.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

The notified polymer contains the quarternary ammonium functional group which is a structural alert for irritation/corrosion and sensitisation (Barrett et al., 1994; Hulzebos et al., 2005). However, given the high molecular weight of the notified polymer and low percentage (< 1%) of low molecular weight species < 1000 Da, the potential for irritation and sensitisation is not expected. Similarly the notified polymer is not expected to cross biological membranes and cause systemic toxicity.

Health hazard classification

As no toxicity data were 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 is expected to be of low hazard. In addition, given the reformulation process is mostly automated and enclosed and workers are expected to use PPE, and the low concentration (up to 3%) in the finished products, the potential for exposure is expected to be limited.

Therefore, the risk to workers associated with the use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

Given the low concentration of the notified polymer in the consumer products (up to 3%) and expected low hazard, the risk to the public from use of the notified polymer is not considered unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia. No significant releases during importation, transportation and distribution are expected from accidental spills of the notified polymer.

Reformulation is expected to occur at one site in Australia. Releases are expected to occur from disposal of empty containers and equipment washing; each may have a loss of up to 1% of the notified polymer. Empty containers are expected to be disposed to landfill or reconditioned. Equipment cleaning waste is expected to be treated on site where the majority of the notified polymer is likely to partition to solids and subsequently be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the notified polymer is expected to be released to sewer nationwide as a result of use in laundry products.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues from empty containers may be disposed of to landfill with the containers.

7.1.2. Environmental Fate

The notified polymer may not be readily biodegradable based on the provided study for the precursor. For the details of the environmental fate studies please refer to Appendix C. Based on the high molecular weight and the high water solubility expected based on the chemical structure, the notified polymer is unlikely to bioaccumulate. Most of the notified polymer is expected to be released to sewer. In a sewage treatment plant (STP), the majority of notified polymer is expected to be adsorbed to sediment for later disposal to landfill. Some of the notified polymer may remain in the water column and be released to surface water with the effluent. In either landfill or surface water, the notified polymer is expected to be finally decomposed via abiotic or biotic pathways, forming water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated assuming for the worst case 100% release of the notified polymer into sewer. A removal rate of 90% is used according to Boethling and Nabholz (1997) for cationic polymers of high molecular weight (> 1000).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	10,000	kg/year
Proportion expected to be released to sewer	100 %	
Annual quantity of chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.4	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	Mitigation
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.61	μg/L
PEC - Ocean:	0.6	μg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 54.5 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m³ and a soil-mixing zone of 10 cm, the concentration of the notified polymer may approximate 0.363 mg/kg in applied soil. This assumes that degradation of the notified polymer occurs in the soil

within 1 year from application. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated biosolids application, the concentration of notified polymer in the applied soil in 5 and 10 years may approximate 1.82 mg/kg and 3.63 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be $1000 \, \text{L/m}^2/\text{year}$ ($10 \, \text{ML/ha/year}$). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density $1500 \, \text{kg/m}^3$). Using these assumptions, irrigation with a concentration of $0.61 \, \mu \text{g/L}$ may potentially result in a soil concentration of approximately $0.004 \, \text{mg/kg}$. 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 $0.02 \, \text{mg/kg}$ and $0.04 \, \text{mg/kg}$, respectively.

7.2. Environmental Effects Assessment

The ecotoxicological investigations for alga conducted on the precursor to the notified polymer are summarised in the table below. Details of the study can be found in Appendix C.

The endpoints for fish and daphnids were calculated based on SAR equations assuming a worst case cation charge density for the polymer (Boethling and Nabholz, 1997). The endpoints are summarised in the table below and have been modified by applying toxicity reduction factors for amphoteric polymers to account for the anticipated binding of the cationic groups with the anionic groups in the polymer. Further mitigation for TOC has not been considered.

Endpoint	Result	Assessment Conclusion
Fish Toxicity (SARS)	96h EC50 > 100mg/L	Not harmful to fish
Daphnia Toxicity (SARS)	48h EC50 > 1000mg/L	Not harmful to daphnids
Algal Toxicity (test on precursor)	72h EC50 > 100mg/L	Not harmful to alga*
	72h NOEC50 = 100mg/I	

^{*} The notified polymer is determined to be potentially not harmful to algae, see Appendix C for details.

The notified polymer is not harmful to aquatic organisms in environmental waters according to the above summarised endpoints. The SARS estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the polymer. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified polymer to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

Under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009) the test substance is not considered acutely harmful to aquatic organisms based on the provided endpoint for alga. Based on the above algal NOEC endpoint for the precursor to the notified polymer, which is not expected to be significantly different from the endpoint for the notified polymer, the notified polymer is not classified for chronic effects to aquatic organisms.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) was calculated using the endpoint for alga which is based on the precursor of the notified polymer. A safety factor of 500 was used since the endpoints for the two trophical levels were estimated using SAR equations instead of studies.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga)	100	mg/L
Assessment Factor	500	
PNEC:	200	μg/L

7.3. Environmental Risk Assessment

Insert the Risk Quotient Table (PEC/PNEC)

Risk Assessment	PEC μg/L	PNEC μg/L	Q
Q - River	0.61	200	0.003
Q - Ocean	0.06	200	0.000

The Risk Quotient (PEC/PNEC) was calculated as < 0.01 for both river and ocean water bodies. The notified polymer is not expected to pose any unreasonable risk to aquatic environment based on the assessed use pattern.

For PBT consideration, the notified polymer may be persistent. It is not considered to meet the criterion for bioaccumulation given the high molecular weight of > 1000 Da and the expected low partition coefficient. It is not considered to meet the criterion for toxicity since it is determined not to be harmful to aquatic life based on the provided study on alga and calculated endpoints for fish and daphnids.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Hydrolysis as a Function of pH

Method Not provided

Remarks The notifier has provided data for hydrolysis stability of the notified polymer, which

indicates a decrease of the pH value from basic (~pH 9) to acidic (~ pH 4) conditions during storage. Based on the provided information, the notified polymer is expected to

hydrolyse in the environmental pH range of 4-9. A study report was not provided.

Test Facility N/A

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1 Environmental Fate

B.1.1 Ready biodegradability

TEST SUBSTANCE Precursor to the notified polymer

METHOD OECD TG 301 B: Ready Biodegradability: CO₂ evolution test.

EC Directive 92/69/EEC C.4-C Method for determination of ecotoxicity:

Ready Biodegradability: Carbon dioxide evolution.

Inoculum Activated sludge

Exposure Period 28 days Auxiliary Solvent None

Analytical Monitoring CO₂ released over a period of 28 days was trapped as BaCO₃ and

determined by titration of the remaining Ba(OH)₂ quantity.

Remarks - Method Activated sewage sludge was exposed to the test substance in duplicates

at 10 mg C/L, $20 - 25^{\circ}\text{C}$ and pH 7.59 - 7.73 in darkness.

A blank control in duplicates with inoculum only and a single reference control with sodium benzoate (962 mg C/L) were conducted for

validation purposes.

RESULTS

Test substance		В	enzoate
Day	% Degradation	Day	% Degradation
10	4.9	5	63.7
28	9.0	28	94.5

Remarks - Results

Degradation of the reference control exceeded 60% at day 5 of the test. A toxicity control was not performed, and therefore, it is unclear if the test substance has inhibition to sludge microbial activity.

The test substance reached a mean biodegradation degree of 9% by day 28 of the test, indicating the test substance is not readily biodegradable. However, as above discussed, effects from toxicity of the test substance to sludge bacteria cannot be excluded for the low degree of biodegradation.

The test substance can be transformed to the notified polymer under acidic conditions. Therefore, the conclusion for the test substance is considered applicable to the notified polymer for biodegradation consideration.

CONCLUSION Under the conditions of this test, the test substance and, by inference,

notified polymer are not readily biodegradable.

TEST FACILITY LISEC (1997)

B.2 Ecotoxicological Investigations

B.2.1 Algal growth inhibition test

TEST SUBSTANCE Precursor to the notified polymer

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species Selenastrum capricornutum (freshwater green algae)

Exposure Period 96 hours

Concentration Range 50, 100 mg/L (nominal)

Auxiliary Solvent None

Water Hardness 170 mg CaCO₃/L

Analytical Monitoring

Remarks - Method

Algal cell densities were determined using a hemacytometer and an Olympus Model BH-2 microscope.

Following a preliminary test at nominal concentrations ranged 1.0-1000 mg/L, a definitive test was performed at $24\pm2^{\circ}C$ and a pH range of 7.5 at start and 8.3-9.0 by 96 hours of the test. The test solutions were prepared by directly diluting the test substance with algal nutrient media for the 100 mg/L solutions and further dilution for the 50 mg/L solutions (nominal). Four replicates were used in each treatment group including the blank control, each with an average day 0 cell density of 1×10^6 cells/mL.

The cell counts were analysed using the one tailed Dunnett's t-test.

RESULTS

Bion	iass	Grow	vth
$72 h E_b C50$	NOEC	E_rC50	NOEC
mg/L at 72 h	mg/L	mg/L at 72 h	mg/L
> 100	100	> 100	100

Remarks - Results

The total cell counts were not statistically significantly different from controls (p<0.05). Based on the nominal concentrations, the 72 h E_bC50 , and E_rC50 for the test substance are determined to be > 100 mg/L, and the 72 h NOEC is determined to be 100 mg/L.

The test substance can be transformed to the notified polymer under acidic conditions by converting hydroxyl groups into acidic functional groups. The addition of anionic groups may be a concern to alga due to the chelating of nutrient elements needed by algae for growth. However, the toxicity to algae is likely to be further reduced due to the presence of calcium ions, which will bind to the functional groups. Based on the above, the above test results are considered not significantly different from the endpoints for the notified polymer. Therefore, the notified polymer is not expected to be harmful to algae.

CONCLUSION

The test substance and, by inference, the notified polymer are not harmful to algae.

TEST FACILITY

ABC Laboratories (1997)

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