File No: LTD/1777

September 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

2-Pyrrolidinone, 1-ethenyl-, polymer with 1-ethenyl-1*H*-imidazole

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/1777	BASF Australia Ltd	2-Pyrrolidinone, 1-ethenyl-, polymer with 1-ethenyl-1*H*-imidazole	Yes	≤ 20 tonnes per annum	Component of laundry detergent

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is 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. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Skin Irritation – Category 2	H315 – Causes skin irritation

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R38: Irritating to skin.

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

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

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

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - Skin Irritation (Category 2): H315 – Causes skin irritation

The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present and the intended use/exposure scenario.

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 to the notified polymer during reformulation:

- use of enclosed, automated processes, where possible

- 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:
  - avoid contact with skin

- 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 polymer:
  - Impervious gloves
  - Goggles
  - Protective clothing

  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

- Where reuse or recycling are not available or practical, dispose of the 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(2) of the Act; if
  - the function or use of the polymer has changed from use as a component of laundry detergent, 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.

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet

The (M)SDS of 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: 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)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2014), China (2013), EU (2007), Japan (2014), Korea (2011), New Zealand (2012), Philippines (2011) and USA (2002)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sokalan® HP 56 K
Sokalan® HP 56 Granules

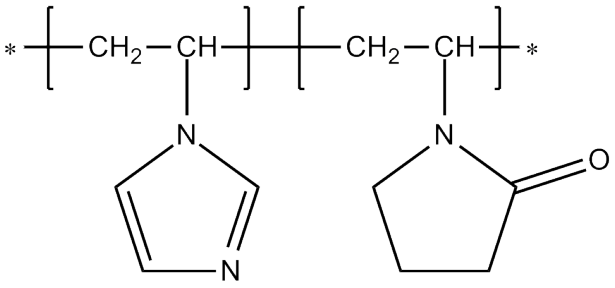
CAS NUMBER
29297-55-0

CHEMICAL NAME
2-Pyrrolidinone, 1-ethenyl-, polymer with 1-ethenyl-1*H*-imidazole

OTHER NAME(S)
Vinylpyrrolidone – vinylimidazole copolymer

MOLECULAR FORMULA
$(C_6H_9NO.C_5H_6N_2)x$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
Number Average Molecular Weight (Mn) > 10,000 Da

ANALYTICAL DATA
Reference IR and GPC data were provided.

3. ANALOGUE DATA
Toxicological data was provided for the human health and environmental effects on a version of the notified chemical which was produced via a different manufacturing process with a significantly lower molecular weight (although still > 1,000 Da) than the notified polymer as proposed for introduction into Australia.

4. COMPOSITION

DEGREE OF PURITY
> 99%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The notified polymer is stable under standard operating conditions and no loss of monomers, reactants, additives or impurities is expected.

DEGRADATION PRODUCTS
The notified polymer is not expected to degrade under normal conditions of use.

5. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: white to yellow granules with product specific odour

Property	Value	Data Source/Justification
Melting Point/Freezing Point	130 °C	(M)SDS
Boiling Point	Not determined	Expected to decompose prior to boiling
Glass transition temperature	176 °C	Measured
Density	1,124 kg/m^3 at 20 °C	Measured
Vapour Pressure	< 1.3 x 10^{-9} kPa	Estimated based on NAMW > 1,000 Da (US EPA 2013)
Water Solubility	≥ 686 g/L at 23 °C	Measured
Hydrolysis as a Function of pH	> 1 year at 25 °C	Measured
Partition Coefficient (n-octanol/water)	log Pow < - 4.8.at 23 °C	Measured
Adsorption/Desorption	Not determined	The notified polymer is expected to adsorb to sediment sludge due to the high molecular weight (> 1000 Da) and potential cationic functional groups
Dissociation Constant	Not determined	The notified polymer contains basic functional groups that have cationic potential
Particle Size	Inhalable fraction (< 100 μm): 0% Respirable fraction (< 10 μm): 0%	Measured
Flash Point	> 100 °C at	(M)SDS
Autoignition Temperature	> 200 °C	(M)SDS
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.

6. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. The notified polymer will be imported into Australia in pure form as granules (Sokalan® HP 56 Granules) or as a component of a liquid mixture (Sokalan® HP 56 K) at a concentration of 30%. There is a possibility that the notified polymer will be imported at up to 0.5% concentration in laundry powder detergents in the future.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 20	≤ 20	≤ 20	≤ 20	≤ 20

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
The notified polymer in its pure form will be imported in 20 kg plastic bags and in the formulated form it will be imported in 1,000 L intermediate bulk containers or 120 kg plastic drums. Within Australia the notified polymer will be distributed by road.

USE
The notified polymer is a dye transfer inhibitor that will be used as a component of domestic laundry detergents at up to 0.5% concentration.

OPERATION DESCRIPTION

Reformulation for liquid laundry detergent
Product containing the notified polymer will typically be transferred from the drum or intermediate bulk container by inserting a dip pipe and pumping to a closed blending tank under local exhaust ventilation. After blending into the liquid laundry detergent, the end-use product containing up to 0.5% of the notified polymer will be transferred via automatic filling machines into appropriate containers for distribution to retail outlets.

Reformulation for powdered laundry detergents
Powdered laundry detergents will be made by a 3 step spray drying process – crutching, spray drying and post addition. Crutching involves mixing detergent raw materials together in a blending vessel to form a thick slurry (containing the notified polymer at up to 1%). The slurry will be transferred from the holding tank to the blend vessel using dedicated pipework and then pumped as a stream of droplets into a spray drying tower and dried to form hollow powder beads. The spray dried beads will then be mixed with small amounts of other dry ingredients to produce laundry powders containing the notified polymer at up to 0.5% concentration. The detergent will then be conveyed to the packaging area for distribution to retail outlets.

End-use
The laundry powder containing the notified polymer at a concentration of < 0.5% will be used to wash clothes in washing machines and may also be used for hand-washing of clothes.

7. HUMAN HEALTH IMPLICATIONS

7.1. Exposure Assessment

7.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Reformulation – Process operators	2 – 4	200
Reformulation – packaging line	4 – 8	200
Reformulation – quality control	2 – 4	200
Transport workers	2 – 4	240
Warehouse staff	2 – 4	240
Retail staff	1 – 2	365

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come in contact with the notified polymer in its pure form or as component of formulated product at a concentration ranging from 30% to > 99% only in the event of accidental rupture of containers.

Reformulation

During reformulation, dermal, ocular and perhaps inhalation exposure of workers to the notified polymer (at up to 99% concentration) may occur during weighing and transfer stages, blending, quality control analysis and cleaning and maintenance of equipment. The notifier states that the exposure is expected to be minimised through the use of enclosed and automated process and PPE such as overalls, goggles, impervious gloves and use of self-contained breathing apparatus where the ventilation is inadequate.

Retail workers

Retail workers may come in contact with the notified polymer at a concentration of up to 0.5% in an event of spill and accidental rupture of containers. The exposure will be mainly dermal though ocular and inhalation may also be possible. The notifier anticipates that the exposure will be minimised by the use appropriate PPE including gloves and protective clothing during clean-up of any spills.

End use

Exposure to the notified chemical (at ≤ 0.5% concentration) in laundry detergents may occur in the cleaning industry. Such professionals may use some PPE to minimise repeated exposure, and good hygiene practices are expected to be in place. If PPE is used, exposure of such workers is expected to be of a similar or lesser extent than that experienced by consumers using products containing the notified chemical.

7.1.2. Public Exposure

There will be widespread and repeated exposure of the public to the notified polymer (at up to 0.5% concentration) through the use laundry detergents. The principal routes of exposure will be dermal, while accidental ocular exposure is also possible during spills and splashes of liquid laundry detergents and inhalation exposure may be possible when using laundry detergent in powder form. It is expected that any spilt material will be washed from the skin.

In addition, household consumers carrying out laundry hand washing have potential for dermal and accidental ocular exposure to the diluted detergent containing the notified polymer at up to 0.5%. The public may also come into incidental contact with wash water containing the laundry detergent at low dilutions.

Significant exposure to the notified polymer from residual remains in washed clothes/linen is not expected to occur as the notified polymer is further diluted in the wash and is expected to be rinsed off from the washed articles prior to drying.

7.2. Human Health Effects Assessment

The results from toxicological investigations conducted on lower molecular weight version of the 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
Rabbit, skin irritation	irritating
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution.
There was no information submitted on the toxicokinetics, metabolism and distribution of the notified polymer. Based on the high molecular weight (> 10,000 Da) the notified polymer is not expected to be absorbed across biological membranes (ECHA, 2012).

Acute toxicity.
An acute oral toxicity study in rats was provided for a lower molecular weight analogue of the notified polymer. An LD50 of > 2,000 mg/kg body weight was established based on no mortality seen at a dose of 2,000 mg/kg body weight.

Irritation and sensitisation.
A lower molecular weight analogue of the notified polymer was found to be a skin irritant when applied dermally to rabbits.

Mutagenicity.
A lower molecular weight analogue of the notified polymer was found to be non mutagenic in a bacterial reverse mutation study.

Health hazard classification
Based on the available information, the notified polymer is 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. The recommended hazard classification is presented in the following table.

Hazard classification	***Hazard statement***
Skin Irritation – Category 2	H315 – Causes skin irritation

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):
R38: Irritating to skin.

7.3. Human Health Risk Characterisation

7.3.1. Occupational Health and Safety
The notified polymer is a skin irritant, however, no systemic toxicity is expected based on the high molecular weight of the notified polymer making it unlikely to be absorbed across biological membranes. There is potential for dermal and ocular exposure of workers to the notified polymer (at up to 99% concentration) during reformulation processes. Exposure should be minimised through the stated use of enclosed, automated processes, local exhaust ventilation and PPE. Commercial laundry workers may be exposed to products containing the notified polymer (at ≤ 0.5% concentration). These workers may use PPE to lower exposure. The risk of irritant effects from the notified polymer at these concentrations is considered to be low, even in the absence of PPE.

Overall, the risk to workers from exposure to the notified polymer is not considered to be unreasonable, given the toxicological profile of the notified polymer and the expected use of engineering controls and PPE.

7.3.2. Public Health
The public may have dermal or ocular exposure to the notified chemical (at ≤ 0.5% concentration) through the use of laundry detergents. The risk of irritant effects from the notified chemical at these concentrations is considered to be low, even in the absence of PPE.

Overall, the risk to public health associated with the proposed use of the notified chemical in detergents and general cleaning products is not considered to be unreasonable.

8. ENVIRONMENTAL IMPLICATIONS

8.1. Environmental Exposure & Fate Assessment

8.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia as a component of a liquid product (up to 30% active), or as a granulated product (up to 100% active) for reformulation processing, or as a component of finished laundry detergent products at a level up to 0.5%.
Products containing the notified polymer will be blended locally to prepare laundry detergent products. The blending and packing processes will occur in semi-automatic and enclosed systems. Release of the notified polymer to the environment from accidental splashes, drips and spills during these processes is not expected to be significant. It is estimated that up to 3% of the imported notified polymer may be released to reformulation sites' effluent systems from the rinsing of blend vessels and filling lines, and residues remaining in empty containers. The effluent containing the notified polymer is expected to be discharged to a single sewage treatment plant and be subsequently discharged to the ocean.

RELEASE OF CHEMICAL FROM USE

During use as a component of laundry products, almost the entire volume of the notified polymer is expected to be released to sewers. Spills are expected to be cleaned up with an appropriate absorbent material, which is expected to be disposed of to landfill, or spills may be washed to sewers. Residues of the notified polymer in the empty containers are likely to be rinsed and added into the washing machine or disposed of to landfill with the empty containers.

RELEASE OF CHEMICAL FROM DISPOSAL

Small amounts of the notified polymer (up to 1% of the import volume) may remain as residues in empty containers, which are expected to be disposed of to landfill along with the empty containers.

8.1.2. Environmental Fate

The notified polymer is not readily biodegradable according to the provided test report. For the details of the environmental fate studies please refer to Appendix C. It is not expected to have potential for bioaccumulation in aquatic organisms given the high molecular weight (>1000 Da).

The majority of the notified polymer is expected to be released to sewage treatment plants (STPs) via domestic wastewater. A small amount of the notified polymer may be sent to landfill as residues in containers or collected wastes from reformulation. Given the high molecular weight of > 1000 Da and the presence of potential cationic functional groups, 90% of the notified polymer released to sewage is expected to be removed from the STP influent (Boethling and Nabholz, 1997) by adsorption to sludge. The sludge containing the notified polymer may be sent to landfill or applied to soils for land remediation. The Notified polymer released to surface waters is expected to partition to suspended soils and organic matter. In water or soil, the notified polymer is expected to ultimately degrade via biotic and/or abiotic processes into water and oxides of carbon and nitrogen.

8.1.3. Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentration (PEC) has been calculated assuming 100% release of the notified polymer nationwide to sewage which is for the worst case scenario. It is also assumed that 90% of the notified polymer will be removed from the STP processes via adsorption to sludge sediment.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	20,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	20,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	54.79	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:	1.21	µg/L
PEC - Ocean:	0.12	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 109 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 0.73 mg/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 3.6 mg/kg and 7.3 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 1.2 µg/L may potentially result in a soil concentration of approximately 8.1 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 40.4 µg/kg and 80.8 µg/kg, respectively.

8.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on a lower molecular weight analogue of the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity*	96 h EC50 > 9400 mg/L	Not harmful to fish
Daphnia Toxicity*	48 h EC50 > 100 mg/L	Not harmful to *Daphnia*
Algal Toxicity*	72 h E_rC50 > 100 mg/L NOEC = 100 mg/L	Not harmful to alga

*Studies conducted on a lower molecular weight analogue of the notified polymer.

The notified polymer is considered to be not harmful to aquatic organisms based on the above endpoints. It is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) for acute and chronic effects to aquatic life.

8.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) was calculated based on the EC50 > 100 mg/L of an analogue polymer for *Daphnia* and alga. A safety factor of 100 was used since endpoints for three trophic levels were available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (*Daphnia* and alga)	> 100	mg/L
Assessment Factor	100	
PNEC:	> 1000	µg/L

8.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	1.21	>1000	**< 0.001**
Q - Ocean	0.12	> 1000	**0.0**

The Risk Quotients (Q = /PNEC) have been calculated to be < 0.1 for river water and ocean water compartments. This suggests an acceptable risk to the aquatic environment from the proposed use of the notified polymer.

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

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Glass Transition Temperature 176 °C

Method	OECD TG 102 Melting Point/Melting Range.
Remarks	No melting temperature was observed between -50 °C and the vaporization of the test substance. A reproducible glass transition was observed.
Test Facility	BASF (2008)

Density 1,124 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids.
Remarks	Duplicate measurements using Pycnometer method.
Test Facility	BASF (2008)

Water Solubility ≥ 686 g/L at 23 °C

Method	OECD TG 105 Water Solubility. EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks	Flask Method was used. A series of mixtures of notified polymer/water were prepared at deferent ratios and stirred for 3 day at 23 °C. The water solubility was determined to be 68.6-79.7 g notified polymer/100 g mixture by visually judgement of the mixtures. The solubility is expected to be ≥ 686 g/L assuming a density of 1000 g/L for the mixtures.
Test Facility	BASF (2009)

Hydrolysis as a Function of pH $t^{1/2}$ > 1 year at 25 °C

Method	OECD TG 111 Hydrolysis as a Function of pH
Remarks	The hydrolytic stability was investigated by measuring 1H-NMR. No hydrolysis was observed within 5 days at 50 °C and pH of 4, 7, and 9. Therefore, the $t_{1/2}$ is expected to be >1 year at 25°C. The notified polymer is considered to be hydrolytically stable.
Test Facility	BASF (2009)

Partition Coefficient (n-octanol/water) log Pow ≤ - 4.8 at 23 °C

Method	Estimated from the single solubilities in octanol and in water
Remarks	The solubility in octanol was determined to be < 10 mg/L at 23 °C. The P_{OW} is therefore estimated to be ≤ 1.46×10^{-5} (< 10 (mg/L)/≥ 686,000 mg/L), which is equivalent to log P_{OW} ≤ - 4.8.
Test Facility	BASF (2009)

Particle Size

Method	ISO13320-1 Laser Diffraction Method.
Remarks	The notified polymer had a particle size between 120 and 2187 µm. There was no material in the test sample determined to have a particle size < 100 µm.
Test Facility	BASF (2008)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: A lower molecular weight analogue of the notified polymer

METHOD
- Species/Strain: Rat/Wistar/ CHBB: THOM (SPF)
- Vehicle: Distilled water
- Remarks - Method: No significant deviation from the OECD protocol.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 M & 5 F	2,000	0

- LD50: > 2,000 mg/kg bw
- Signs of Toxicity: One day after the administration of the test substance, signs of toxicity were observed in male and female rats. Two of the male rats showed impaired general state, dyspnoea, staggering and piloerection and one female rat showed impaired general state, dyspnoea and piloerection. It was not mentioned as to whether the symptoms were seen in the same rat or different rats or when the symptoms resolved. The weight gains measured on the treatment day, day 7 and 14 showed no adverse effect of the test substance on the weight gain.
- Effects in Organs: None
- Remarks - Results: The LD50 was derived based on an absence of mortality during the test.

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

TEST FACILITY: BASF (1994a)

B.2. Irritation – skin

TEST SUBSTANCE: A lower molecular weight analogue of the notified polymer

METHOD
- Species/Strain: Rabbit/White Vienna
- Number of Animals: 3 (1 male and 2 females)
- Vehicle: Distilled water
- Observation Period: 8 days
- Type of Dressing: Semi-occlusive.
- Remarks - Method: No significant deviations from the OECD protocol.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	2.00	2.66	2.33	3	< 8 days	0
Oedema	0.33	1.66	0.33	3	< 8 days	0

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

- Remarks - Results: All three of the test animals showed scaling on the skin at the day 8 observation.

CONCLUSION: The test substance is irritating to the skin.

TEST FACILITY BASF (1994b)

B.3. Genotoxicity – bacteria

TEST SUBSTANCE A lower molecular weight analogue of the notified polymer

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure and Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98 & TA100
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 20, 100, 500, 2,500 and 5,000 µg/plate b) Without metabolic activation: 20, 100, 500, 2,500 and 5,000 µg/plate
Vehicle	Distilled water
Remarks - Method	No significant deviations from the OECD protocol. Vehicle and positive controls were used in parallel with the test substance. Positive control: i) without S9: N-methyl-N'-nitro-N-nitrosoguanidine (TA100 and TA1535), 4-Nitro-o-phenylendiamine (TA98) & 9-Aminoacridine (TA1537); ii) with S9: 2-Aminoanthracene (TA98, TA100, TA1535 and TA1537).

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1 (Plate incorporation)	> 5,000	> 5,000	Negative
Test 2 (Pre incubation)	≥ 2,500	> 5,000	Negative
Present			
Test 1 (Plate incorporation)	> 5,000	> 5,000	Negative
Test 2 (Pre incubation)	≥ 2,500	> 5,000	Negative

Remarks - Results There was no significant change in the number of revertant colonies observed with any of the test substance concentrations when compared to vehicle control.
The positive controls gave satisfactory responses confirming the validity of the test system.

CONCLUSION The test substance was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY BASF (1994c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	A lower molecular weight analogue of the notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test (Modified Sturm Test)
Inoculum	Activated sludge
Exposure Period	29 days
Auxiliary Solvent	Not applied
Analytical Monitoring	The amount of CO_2 at the end of the test was compared with the calculated theoretical CO_2-production ($ThCO_2$) for expression of the degradation degree
Remarks - Method	The study followed the above test guideline and good laboratory practice (GLP) principles. The test was conducted in duplicate at a concentration of 38.5 mg/L approximates to 20.0 mg/L DOC. Tests of blank control (duplicate), reference control and toxicity control were also conducted.

RESULTS

Test substance		Sodium benzoate	
Day	*% Degradation*	*Day*	*% Degradation*
3	2	7	70
29	7	29	97

Remarks - Results	All the test validity criteria were met. The toxicity control reached 54% degradation by 29 day, indicating the test substance is not toxic to the micro-organisms. The test results in the table above indicate that the test substance is not readily biodegradable. The test substance is considered to be an acceptable analogue of the notified polymer. Therefore, the notified polymer is not expected to be aerobically readily biodegradable.
CONCLUSION	The test substance and, by inference, the notified polymer are not readily biodegradable
TEST FACILITY	BASF (1994d)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	A lower molecular weight analogue of the notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test –Static Test
Species	Zebra fish
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	The test concentrations were measured using a pyrolysis gas chromatograph
Remarks – Method	The study followed the above test guideline and good laboratory practice (GLP) principles. Based on the outcome of two range-finding tests, the definitive test was conducted at four test concentrations up to 10,000 mg/L (nominal).

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual (96 h)*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	0	10	0	0	0	0	0
50	38	10	0	0	0	0	0
100	99.3	10	0	0	0	0	0
5,000	4980	10	0	0	0	0	0
10,000	9400	10	0	0	0	0	0

LC50	> 9,400 mg/L at 96 hours (measured)
NOEC	9,400 mg/L at 96 hours (measured)
Remarks – Results	All the test validity criteria were met. No mortality or sublethal effects were observed at all test levels. The test substance is not expected to be harmful to fish based on the test outcome. The test substance is considered to be an acceptable analogue of the notified polymer. Therefore, the notified polymer is not expected to be harmful to fish.
CONCLUSION	The test substance and, by inference, the notified polymer are not harmful to fish
TEST FACILITY	BASF (1994e)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	A lower molecular weight analogue of the notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test – Static Test
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	2.44 mmol $CaCO_3$/L
Analytical Monitoring	The details regarding test concentrations analysis were not provided
Remarks - Method	The study followed the above test guideline and good laboratory practice (GLP) principles. The test was conducted at four concentrations ranging from 100 to 12.5 mg/L with a dilution factor of 2.

RESULTS

Concentration mg/L	*Number of D. magna*	*Number Immobilised*	
Nominal		*24 h*	*48 h*
Control	20	0	0
12.5	20	0	0
25	20	0	1
50	20	0	0
100	20	0	0

LC50	> 100 mg/L at 48 hours (nominal)
NOEC	100 mg/L at 48 hours (nominal)
Remarks - Results	All the test validity criteria were met. The test concentrations at 48 hour were indicated to be in the range of 94.8%-115.5% of the nominal concentrations. No details were provided. The endpoints are presented based on nominal concentrations. No dose response effects were observed at all the test levels. The test substance is not expected to be harmful to *Daphnia* based on the test results. The test substance is considered to be an acceptable analogue of the notified polymer. Therefore, the notified polymer is not expected to be harmful to *Daphnia*.
CONCLUSION	The test substance and, by inference, the notified polymer, are not harmful

to *Daphnia*

TEST FACILITY BASF (1994f)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE A lower molecular weight analogue of the notified polymer

METHOD OECD TG 201 Alga, Growth Inhibition Test

Species	
Exposure Period	72 hours
Concentration Range	Nominal: 0.39, 0.78, 1.56, 3.13, 6.25, 12.5, 25, 50, 100 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	The details regarding test concentrations analysis were not provided
Remarks - Method	The study followed the above test guideline and good laboratory practice (GLP) principles.

RESULTS

Biomass		*Growth*	
E_bC50	*NOEC*	*E_rC50*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
> 100	3.13	> 100	100

Remarks - Results All the test validity criteria were met. The test concentrations at 72 hour were indicated recoveries of 80% - 105%. No details were provided. The endpoints are presented based on nominal concentrations.
No significant inhibitory effects were observed at all test levels. An inhibition of 13.1% based on biomass was observed at the concentration of 6.25 mg/L, and an inhibition of 7.1% based on growth rate was observed at the top test level of 100 mg/L. The test substance is not expected to be harmful to alga based on the test results.
The test substance is considered to be an acceptable analogue of the notified polymer. Therefore, the notified polymer is not expected to be harmful to alga.

CONCLUSION The test substance and, by inference, the notified polymer are not harmful to alga

TEST FACILITY BASF (1994g)

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