File No PLC/982

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN FULL PUBLIC REPORT

Polymer in SOKALAN RO 1000

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government 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 Australian Government Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Full 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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1. APPLICANT AND NOTIFICATION DETAILS

Applicants
BASF Australia Ltd (ABN 62 008 437 867)
Level 12, 28 Freshwater Place SOUTHBANK VIC 3006

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, polymer constituents, residual monomers/impurities and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)
SOKALAN RO 1000
SOKALAN PM 15 I
SOKALAN PM 10 I

Molecular Weight
Number Average Molecular Weight (Mn) is > 1,000 Da

Reactive Functional Groups
The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Colourless to brownish liquid with faint odour (sales product).
Melting Point	> 150°C
Density	1270 kg/m^3 at 23°C (Sokalan RO 1000)
Water Solubility	The water solubility is expected to be ≥ 250 g/L (pH dependent) as it is present at up to 25% in aqueous solution. The presence of polar functionalities and log P_{ow} of the notified polymer (< -2) are indicative of highly hydrophilic behaviour.
Dissociation Constant	Not determined. The notified polymer is a salt and is expected to be ionised in the environmental pH range (4-9).
Particle Size	Imported in aqueous solution
Reactivity	Stable under normal environmental conditions

Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-10	1-10	10-30	30-50	50-100

Use
The notified polymer will not be manufactured in Australia. It will be imported as a 20 – 25% w/w component of an aqueous solution of a polycarboxylate, sodium salt in water. The aqueous solution will be imported by sea in 1000 L intermediate bulk containers or 250 kg drums.

Upon arrival at ports in Perth, Sydney, Melbourne and Brisbane, the notified polymer will be transported by road to a contracted warehouse where it will be stored under cover until required for distribution to customers, typically water management companies.

The notified polymer will be used for reverse osmosis membrane anti-scalant applications for controlling the deposition of inorganic scale forming salts on membrane surfaces.

6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by tests submitted on the following toxicological endpoints.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
1. Rat, acute oral	LD50 > 2000 mg/kg bw	no	OECD TG 401
2. Rabbit, skin irritation	non-irritating	no	OECD TG 404
3. Rabbit, eye irritation	non-irritating	yes	OECD TG 405
4. Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD TG 471

All results were indicative of low hazard. Mild to moderate conjunctival irritation was observed 1 hour post-exposure, however all effects were resolved by 48 hours.

Occupational Health and Safety Risk Assessment
The OHS risk presented by the notified polymer is expected to be low, based on the assessed likely low exposure of workers and the low intrinsic hazard of the polymer.

Public Health and Safety Risk Assessment
As there will be no exposure of the public to the notified polymer (or products containing the notified polymer) the risk to the public from exposure to the notified polymer is considered to be negligible. Where exposure occurs at very low concentrations (50 ppb) in produced water, the low hazard of the polymer translates to low risk.

7. ENVIRONMENTAL RISK ASSESSMENT

Hazard characterisation
Generally, this type of polyanionic polymer will not be toxic to fish or daphnids, with a LC50 > 100 mg/L. This is supported by environmental endpoints observed in testing conducted on the notified polymer.

Endpoint	*Result*	*Assessment Conclusion*
Fish toxicity	LC50 > 100 mg/L	Not harmful to fish

Anionic polymers are known to be moderately toxic to algae. The mode of toxic action to algae is over-chelation of nutrient elements needed by algae for growth. This mode of action is expected for the notified polymer due to its use as a chelating agent in the control of inorganic scale. The ChV for green algae for the notified polymer is estimated, using the nearest analogue approach, to be 93.0 mg/L (Boethling RS & Nabholz JV, 1997). In this case, as algae are considered to be the most sensitive species and as a chronic endpoint is available, an assessment factor of 10 is considered suitable, and the resultant Predicted No Effect Concentration (PNEC) is 9.3 mg/L. The toxicity to algae is likely to be reduced due to the presence of calcium ions in receiving waters, which will bind to the functional groups.

Boethling RS & Nabholz JV (1997) Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton JD & Sutcliffe R, ed. Ecological Assessment of Polymers; Strategies for product stewardship and regulatory programs. New York, Van Nostrand Reinhold, pp 187–234.

Environmental Risk Assessment
Release to the environment during shipping, transport and warehousing is expected to be minimal and any spills are expected to be handled by physical containment, collection and subsequent safe disposal. Up to 1% of the notified polymer is estimated to be retained in import containers and these residues are expected to be rinsed out and disposed of to sewer. The majority of the notified polymer will be released directly into the aquatic environment (brackish or ocean water) point sources in discharge waters following use as an anti-scalant. The concentration of the notified polymer in discharge waters at point sources may be up to 1.85 mg/L for water released into inland brackish waters and up to 6.39 mg/L for waters released into ocean waters. Assuming a worst case scenario, dilution of 1 for brackish waters and 10 for ocean water results in PECs of 1.85 mg/L and 0.64 mg/L respectively.

The notified polymer is expected to be hydrolytically stable in the environmental pH range and is not expected to be readily biodegradable due to its high molecular weight. The notified polymer is not expected to cross biological membranes due to its high molecular weight and thus it is unlikely to bioaccumulate. The notified polymer is soluble in water, but due to its anionic nature, is likely to be immobilised via adsorption onto soil particles and sediments in the aquatic environment. It is expected to disperse and eventually degrade through biotic and abiotic processes to form water and oxides of carbon.

The Risk Quotient (Q) has been derived by dividing the PEC by the PNEC:

Risk Assessment	***PEC mg/L***	***PNEC mg/L***	***Q***
Q – Brackish:	1.85	9.3	0.20
Q – Ocean:	0.64		0.069

As the Q value is below 1 for both brackish and ocean waters, the notified polymer is not considered to pose an unreasonable risk to the environment. Also, due to its use as scale inhibitor, it is expected that some if not the majority of the notified polymer will be released to the environment chelated with Ca^{2+} and/or Mg^{2+}, thereby further mitigating the potential for algal toxicity.

8. RECOMMENDATIONS

Human Health Risk Assessment
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

Environmental Risk Assessment
Based on the assumed low hazard and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Health and Safety Recommendations

- 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.

Environmental Recommendations
- No specific control measures are required to minimise release of the notified polymer to the environment.

Disposal
- The notified polymer should be disposed to landfill.

Storage
- The following precautions should be taken by workers regarding storage of the notified polymer:
  - Store in a segregated and approved area.
  - Store in original container protected from direct sunlight in a dry, cool and well ventilated area, away from incompatible materials (oxidising substances, strong acids, strong bases).

Emergency Procedures

- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.
- Spills and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

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 polymer 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 notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the notified polymer has changed from reverse osmosis membrane anti-scalant for water treatment, or is likely to change significantly;
- the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
- the notified polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical 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 product containing the notified polymer was provided by the applicant. The accuracy of the information on the MSDS remains the responsibility of the applicant.