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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Dow Corning 3055 Resin

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 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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

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/1683	Dow Corning Australia Pty Ltd	Polymer in Dow Corning 3055 Resin	ND*	≤ 50 tonne/s per annum	Component of industrial coatings

*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).

The environmental hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute Category 1	H400 - Very toxic to aquatic life
Chronic Category 1	H410 - Very toxic to aquatic life with long lasting effects

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 a 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 to the notified polymer as introduced and during reformulation of coatings (at > 80% concentration):
  - Local exhaust ventilation during reformulation of coatings
  - Enclosed, automated processes when possible

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified polymer as introduced and during reformulation of coatings (at > 80% concentration) or in formulated products (at approximately 50%):

- Avoid contact with skin and eyes
- Maintain good hygiene practices

- 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:
  - Chemical resistant gloves (introduction and reformulation)
  - Gloves (formulated products)
  - Safety glasses or face mask
  - Coveralls

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012) or relevant State or Territory Code of Practice.

- 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.

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 1000 Da;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from component of industrial coatings, 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 MSDS of the product containing 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

This notification has been conducted under the cooperative arrangement with the United States Environmental Protection Agency (US EPA). Information pertaining to the assessment of the notified polymer by the US EPA was provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment, including the recommendations on safe use of the notified polymer, were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Dow Corning Australia Pty Ltd (ABN: 36 008 444 166)
Darling Park, Tower 2, Level 20, 201 Sussex Street
SYDNEY NSW 2000

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 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 and import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA EPA (2012)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Dow Corning 3055 Resin (containing the notified polymer at > 80% concentration)

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: colourless to pale yellow liquid

Property	Value	Data Source/Justification
Boiling Point	> 500 °C at 101.3 kPa	Estimated
Density	1050 kg/m^3 at 25 °C	MSDS
Vapour Pressure	Not determined	Expected to be low based on the high molecular weight.
Water Solubility	Not determined	Expected to be very low as the notified polymer is cross-linked, has predominantly hydrophobic structure and high molecular weight.
Hydrolysis as a Function of pH	Not determined	Does not contain readily hydrolysable functionalities.
Partition Coefficient (n-octanol/water)	Not determined	The hydrophobic nature of the notified polymer indicates a strong potential to partition into the octanol phase.
Adsorption/Desorption	Not determined	Expected to be relatively immobile in soil based on its highly hydrophobic structure.
Dissociation Constant	Not determined	The notified polymer has a potential to ionise under environmental conditions (pH 4-9).
Particle Size	Not determined	Liquid
Flash Point	> 121 °C	MSDS
Flammability	Not determined	Not expected to be flammable under normal conditions of use.
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties.

DISCUSSION OF PROPERTIES

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

Physical hazard classification
Based on the limited 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 into Australia at > 80% concentration to be reformulated into finished industrial coating products at approximately 50% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-30	10-30	10-30	20-50	20-50

PORT OF ENTRY
Sydney

IDENTITY OF RECIPIENTS

Dow Corning Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The paint containing the notified polymer will be packed, stored and transported in 20 kg pail or 200 kg steel drums and it will be transported by road from the notifier's warehouse to the paint industry.

USE
Paint additive used in protective industrial coatings.

OPERATION DESCRIPTION
Reformulation
The notified polymer (> 80% concentration) will be formulated into various coating products (containing approximately 50% notified polymer). Reformulation will be mostly an automated process. The notified polymer will be transferred from the drum, possibly by metered dosing, into a closed mixing vessel where it will be mixed with other ingredients. Samples will then be taken for quality control purposes. Filling containers with the final product (containing approximately 50% notified polymer) will be an automated process conducted under exhaust ventilation.

End use - Professionals
The formulated coating products (containing about 50% notified polymer) will be mixed with another component and subsequently applied to various substrates by brush, roller or spray.

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)*
Stevedoring worker	1	5
Transport	2	5
Warehouse	5	10
Formulators	8	60
Coaters	8	60

EXPOSURE DETAILS
Transport and storage
Storage and transport workers are not expected to be exposed to the notified polymer, except in the unlikely event of an accidental container rupture.

Reformulation
Dermal, ocular and possibly inhalation exposure of workers to the notified polymer (at > 80% concentration) may occur during transfer processes, blending, cleaning and maintenance tasks. However, exposure is expected to be minimised by the use of mostly automated processes, local exhaust ventilation and appropriate personal protective equipment (PPE), including protective clothing, impervious gloves and goggles.

End use - Professionals
Professionals (e.g painters) may be exposed to coatings containing the notified polymer (at approximately 50% concentration). Exposure is expected to occur predominantly via the dermal route, with ocular and inhalation exposure also possible, particularly when products are applied by spray. The potential for exposure should be minimised through the use of safe work practices, local exhaust ventilation, good general ventilation or forced mechanical ventilation and PPE by workers (goggles, impervious gloves, appropriate clothing and perhaps respiratory protection during spray application). When applied by spray, ventilated, automated and enclosed spray booths will usually be used. If products containing the notified polymer are applied by spray outside a spray booth, respirators are expected to be worn to avoid inhalation of the aerosol.

6.1.2. Public Exposure

There is negligible potential for public exposure to the notified polymer as it will only be used for industrial applications and once cured the notified polymer will be bound within a polymer matrix and will not be bioavailable.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer.

Based on the high molecular weight (> 1000 Da) of the notified polymer, the potential of the notified polymer to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure is expected to be limited. However, the polymer contains a proportion of low molecular weight species (< 1000 Da) that may be absorbed. In addition, the notified polymer may be absorbed across the respiratory tract, based on its expected hydrophobic nature.

The notified polymer contains a structural alert indicative of possible irritation effects. Therefore, the potential for skin and eye irritation of the notified polymer cannot be ruled out.

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 contains a structural alert for irritation and thus such effects cannot be ruled out.

Dermal, ocular and inhalation exposure of workers to the notified polymer at the imported concentrations of > 80% may occur during reformulation of coatings. Such exposure may result in irritation effects. The use of engineering controls (particularly the automation of processes and local exhaust ventilation) and personal protective equipment (skin and eye protection) during the reformulation of coatings is expected to minimise exposure and reduce the risk of such effects.

Dermal, ocular and inhalation exposure of workers to the notified polymer at approximately 50% may occur during coating application (spray, brush or roller). At these concentrations, the risk of irritation from the notified polymer is expected to be minimised by the engineering controls, such as spray booths, and personal protective equipment, such as gloves and overalls.

Under the proposed usage conditions, the risk of the notified polymer to workers is not considered to be unreasonable.

6.3.2. Public Health
The products containing the notified polymer will not be available to the public. The public may come into contact with surfaces of cured and dried products containing the notified polymer. The notified polymer will be incorporated into the matrix of the paint and will not be bioavailable. Therefore the risk to the public from the use of the notified polymer is not expected to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will not be manufactured in Australia; therefore, there will be no release from this activity. During reformulation activities, the notified polymer will be mixed with other ingredients (e.g. resins, pigments, additives and solvents) at the formulation site. Mixing will be done in closed mixing chambers. The formulation equipment will be cleaned by washing with solvent. The liquid/solvent waste will be treated as site industrial waste and will be collected by licensed disposal contractors for recycling. Solid waste will be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The main release of the notified polymer from end-use is expected from cleaning of application equipment, overspray, spills, and leaks. Spills are expected to be collected by professional users or by engineering controls by the industrial users. The collected wastes and empty containers are expected to be disposed of to landfill. Application equipment is expected to be cleaned by washing with solvent. The solvent waste is expected to be disposed of according to local/state regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Applied notified polymer in coatings is expected to share the fate of various substrates to which it has been applied. The notified polymer is likely to be either thermally decomposed during metal reclamation processes or disposed of to landfill at the end of the useful life of the coated article.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified polymer is expected to be cured within an inert polymer matrix adhering to articles following its use in coating applications. The notified polymer has a tendency to sorb to surface boundaries based on its expected low water solubility and potential cationicity. The notified polymer that may be released to sewers is expected to mainly partition to sludge, and be disposed of to landfill. Consequently, it is not anticipated to be significantly bioavailable to aquatic organisms. Given that the notified polymer has a relatively high molecular weight, it is not expected to bioaccumulate as it is too large to cross the biological membranes. Notified polymer that is disposed of to landfill is expected to remain associated with the substrate to which it has been applied. In its cured form it is not expected to be mobile, bioavailable or biodegradable. Ultimately, the notified polymer is expected to eventually degrade via biotic and abiotic processes in landfill, or by thermal decomposition during metal reclamation processes, to form water and oxides of carbon, nitrogen and silica.

7.1.3. Predicted Environmental Concentration (PEC)

Whilst coatings containing the notified polymer are expected to be cleaned with solvent, the Predicted Environmental Concentration (PEC) was calculated conservatively assuming that 5% of the total import volume of polymer would be released to sewer annually due to washing of application equipment by end users. It was assumed that 90% of the notified polymer partitions to sludge in Sewage Treatment Plants (STPs) as it is a polymer with potential cationicity (Boethling and Nabholz, 1997) and the release of the notified polymer will occur over 260 days per annum into the total Australian effluent volume. This corresponds to release only on working days, based on a 5 day work week. The results of the calculation are shown in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	50,000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	2,500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	9.62	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	
Dilution Factor - Ocean	10	
PEC - River:	0.21	µg/L
PEC - Ocean:	0.02	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 19.1 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 polymer may approximate 0.13 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 0.64 mg/kg and 1.28 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 polymer 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 0.21 µg/L may potentially result in a soil concentration of approximately 1.42 µg/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 7.1 µg/kg and 14.2 µg/kg, respectively.

7.2. Environmental Effects Assessment

Environmental effect endpoints for the notified polymer are presented in the table below.

Endpoint	*Result (mg/L)*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) = 1.5	Toxic to fish
Daphnia Toxicity	EC50 (48 h) = 1.4	Toxic to aquatic invertebrates
Algal Toxicity	*E_rC50 (72 h) = > 0.3	Very toxic to algae

* E_rC50 (72 h) was regarded as 0.3mg/L for Predicted No-Effect Concentration (PNEC) calculation as it was very close to E_rC49 (72 h) value, which was 0.3 mg/L.

In a 96-hour fish toxicity test, *Oncorhynchus mykiss* (7 animals/one replicate) were exposed to the notified polymer at nominal concentrations of 0.63, 1.3, 2.5, 5.0 and 10 mg/L under static conditions. Dimethylformamide (DMF) was used as a solvent. During the study, water temperature was 12.2 °C, pH ranged from 7.5 – 8.2, and the dissolved oxygen concentrations were ≥ 8.8 mg/L. The water hardness ranged between 105 to 120 mg $CaCO_3$/L. Although there was only one replicate tested, the study is acceptable. An *O. mykiss* 96-hour LC50 of 1.5 mg/L was reported.

In a static 48-hour immobilisation toxicity test, *Daphnia magna* (10 daphnia/2 replicates/test concentration) were exposed to the notified polymer at nominal concentrations of 0.19, 0.38, 0.75, 1.5, and 3.0 mg/L, a dilution water control and a solvent control (0.1 mL/L dimethylformamide). All daphnids in the negative and solvent control groups and in the 0.19 and 0.38 mg/L treatment groups appeared normal throughout the test, with no mortalities or overt signs of toxicity observed. Percent immobility in the 0.75, 1.5 and 3.0 mg /L treatment groups was 5, 75 and 85%, respectively. During the study, water temperature was 20± 1 °C, the pH ranged from 8.2 – 8.6 and the dissolved oxygen concentrations were ≥ 8.2 mg/L. The water hardness ranged between 105 to 120 mg $CaCO_3$/L. The 48-hour EC50 value of 1.4 mg/L was reported and the NOEC was 0.38 mg/L. This study is acceptable.

In a static 72-hour algal growth inhibition test, *Pseudokirchneriella subcapitata* (1 × 104 cells/mL) were exposed to the notified polymer at nominal concentrations of 0.019, 0.038, 0.075, 0.15, and 0.30 mg/L, a dilution water control and a solvent control (0.1 mL/L dimethylformamide (DMF)). There were three replicates per test concentration. EPA guidelines and OECD guidelines recommend using six replicates for controls chambers when conducting algal toxicity tests. The pH ranged from 7.6 to 8.2. The test vessels were sterile 250-mL Erlenmeyer flask placed in an incubator and positioned on rotary shakers set at approximately 100 rpm with the temperature maintained at 24 ± 2 °C under continuous cool white fluorescent lighting at a range of 412 – 825 foot-candles (4440 - 8880 lux). Samples for cell counts were collected from each test vessel at 24, 48, and 72 hours. The samples were diluted with Isoton®II diluents solution and counted using a Coulter® Counter. For data analysis, cell densities were used to calculate the average specific growth rate and yield. Average specific growth rate from day 0 through 72 hours was calculated. Yield was calculated as the biomass (cell density) at any time point minus the starting biomass. After 72-h of exposure, inhibition of yield ranged from 14% in the 0.019 mg/L treatment group to 89% in the 0.30 mg/L treatment group. Dunnett's test revealed that yield was significantly reduced in the 0.038, 0.075, 0.15 and 0.30 mg/L treatment groups in comparison to the solvent control ($p \leq 0.05$). After 72-h of exposure, inhibition of growth rate ranged from 3.9% in the 0.019 mg/L treatment group to 49% in the 0.30 mg/L treatment group. Dunnett's test revealed that yield was significantly reduced in the 0.075, 0.15 and 0.30 mg/L treatment groups in comparison to the solvent control ($p \leq 0.05$). The 72-hour EC50 is 0.072 mg/L for yield and greater than 0.30 mg/L for growth rate. The 72 hour NOEC is 0.019 mg/L (yield) and 0.038 mg/L (growth rate).

Based on the endpoints for the notified polymer, it is expected to be very toxic to algae while it is toxic to fish and aquatic invertebrates. Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009), the notified polymer is formally classified as Acute Category 1; Very Toxic to aquatic life. Based on the acute toxicity of the notified polymer and lack of data on potential for biodegradation, it has been formally classified under GHS as Chronic Category 1; Very toxic to aquatic life with long lasting effects.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) was calculated based on the endpoint for the most sensitive species (algae, E_rC50) and an assessment factor of 100. The conservative assessment factor of 100 was used since three measured ecotoxicological data of three trophic levels were available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Invertebrates).	0.30	mg/L
Assessment Factor	100	
PNEC:	3.00	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	*PEC µg/L*	*PNEC µg/L*	*Q*
Q - River:	0.21	3.0	0.071
Q - Ocean:	0.02	3.0	0.007

The Risk Quotients (RQ = PEC/PNEC) for a conservative discharge scenario have been calculated to be < 1 for the river and ocean compartments. The notified polymer is not likely to bioaccumulate based on its high molecular weight. Although the notified polymer is very toxic to aquatic species, it is unlikely to result in ecotoxicologically significant concentrations in aquatic environment for the assessed use pattern. Therefore, it is expected that there is no unreasonable risk to the aquatic environment from the assessed use scenario.

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