File No PLC/1136

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymers with 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane and reduced Me esters of reduced polymd. oxidized tetrafluoroethylene, compds. with triethylamine

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 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

July 2013

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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
PLC/1136	Solvay Interox Pty Ltd	Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymers with 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane and reduced Me esters of reduced polymd. oxidized tetrafluoroethylene, compds. with triethylamine	No	≤15 tonnes per annum	Component of water repellents for carpets and rugs

CONCLUSIONS AND REGULATORY OBLIGATIONS

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 assessed use pattern, the notified polymer is not expected 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.

- 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.

- If aerosols are formed during the use of the notified polymer, engineering controls and respiratory protection should be used to prevent inhalation exposure.

- 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.

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 of to landfill.

Emergency Procedures

- 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 a component of water repellents for carpets and rugs, 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 notified polymer on occupational health and safety, public health, or the environment.

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

(Material) Safety Data Sheet

The (M)SDS of the notified polymer was provided by the applicant. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants

Solvay Interox Pty Ltd (ABN 70 000 882 137)
20-22 McPherson Street
Banksmeadow NSW 2019

Exempt Information (Section 75 of the Act)
Data items and details claimed exempt from publication: molecular formula, molecular weight, polymer constituents, residual monomers/impurities and use details.

2. IDENTITY OF POLYMER

Marketing Name(s)
Fluorolink P56 (containing up to 25% notified polymer)

Chemical Name
Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymers with 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane and reduced Me esters of reduced polymd. oxidized tetrafluoroethylene, compds. with triethylamine

CAS Number
328389-91-9

Molecular Formula
Unspecified

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

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	Amber water dispersion*
Melting Point/Glass Transition Temp	Not determined
Density	1100 kg/m^3 at 20 °C*
Water Solubility	Expected to be water dispersible based on the presence of hydrophilic functionality and its use in aqueous products
Dissociation Constant	Not determined. The notified polymer contains anionic functionalities which will be ionised under the environmental conditions (pH 4-9)
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

*For imported product

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	2-7	10-15	10-15	10-15	10-15

Use
The notified polymer will not be manufactured in Australia. The notified polymer will be imported into Australia as an aqueous dispersion containing the notified polymer at up to 25% concentration. Products containing the notified polymer (up to 4% concentration) will be reformulated in Australia. The final products will be applied to carpets and rugs in industrial carpet mills using foam, spray or exhaust application methods.

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 with the notified polymer (at ~25% concentration) 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. Rat, acute dermal	LD50 > 2000 mg/kg bw	no	OECD TG 402
3. Rabbit, skin irritation	slightly irritating	yes	OECD TG 404
4. Rabbit, eye irritation	non-irritating	no	OECD TG 405
5. Skin sensitisation - non-adjuvant test	no evidence of sensitisation	no	OECD TG 406
6. Genotoxicity - bacterial reverse mutation	non-mutagenic	no	OECD TG 471

All results were indicative of low hazard. In the skin irritation study, slight erythema was observed at 1 hour with complete recovery after 24 hours.

Workers handling the notified polymer during reformulation or application to carpets are expected to wear PPE including gloves, safety goggles and long sleeved clothing. Air curtains will be used during spray application to collect overspray.

The notified polymer is intended for industrial applications only and the public will only be exposed to the notified polymer in treated carpets and rugs. Given the low hazard and the assessed use pattern, the risk posed by exposure to the notified polymer is not considered unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

The ecotoxicological investigations were conducted on the product containing the notified polymer. The endpoints for fish, daphnia and algae were reported by the notifier based on the concentrations for the test item. However, the notified polymer only contains < 25% of the notified polymer and the actual toxicity of the notified polymer may be under estimated. The actual results as summarised in the table below were calculated based on the original reported results and the percentage of active component in the test item.

Endpoint	*Result*	*Assessment Conclusion*	*Test Guideline*
Fish Toxicity	LC50 (96 h) > 25 mg/L	May be harmful to fish	OECD TG 203
Daphnia Toxicity	EC50 (48 h) > 25 mg/L	May be harmful to aquatic invertebrates	OECD TG 202
Algal Toxicity	E_rC50 (72 h) > 25 mg/L	May be harmful to algae	OECD TG 201

The notified polymer will be manufactured overseas and reformulated locally into the finished products for use as water repellent on carpets/rugs. During reformulation processes, waste generated from accidental spills, equipment cleaning and residues in empty import containers is expected to be collected with inert material, contained and disposed of according to local regulations. The final products containing the notified polymer will be applied to carpets and rugs in industrial carpet mills using foam, spray or exhaust application methods. It is estimated by the notifier that 7% (= 2% from foam or spray applications + 5% from exhaust application) of the total import volume of the notified polymer will be released to on-site waste treatment system and treated according to local regulations. After the on-site treatment, the notified polymer is expected to be finally released to public sewer.

The notified polymer is expected to be applied predominantly to carpets/rugs. The notified polymer may become dissociated from treated fabrics during vacuuming and cleaning activities. According to a test conducted by the notifier, up to 50% (≤ 7500 kg) of the notified polymer was indicated to be removed by hot water extraction cleaning and be released to sewer. The majority of the notified polymer is expected to end up in landfill at the end of the carpet's lifetime or to be disposed of to landfill as solid waste from regular vacuuming. Abrasion of the floor surface by foot traffic is expected to result in some relocation of the notified polymer. Estimates for losses due to abrasion from these uses are not available.

The notified polymer disposed of to landfill in the form of solid waste from carpet vacuuming or when disposing of used carpet is expected to associate with the articles. In this form, the notified polymer is unlikely to be mobile or bioavailable. Notified polymer released to sewer in washing water from carpet cleaning processes is not expected to be efficiently removed in sludge sewage treatment plant (STP). The notified polymer contains anionic functionality and has a molecular weight of more than 5000 Da, which indicates the notified polymer has a potential be removed in STP processes through partitioning to sludge. However, the usual predictive models for partitioning during sewage treatment are inapplicable for polyfluoroalkylated compounds such as the notified polymer. The typical models assume lipophilicity for hydrophobic functionality whereas the fluorinated functionality is both hydrophobic and lipophobic. The assumption that surface activity and/or high molecular weight results in efficient removal by sorption to sludge during conventional wastewater treatment has not been verified by supporting data for this class of polymer either. Therefore, a significant proportion of the notified polymer may remain in the aqueous phase following wastewater treatment noting its potential of being both hydrophobic and lipophobic.

Under a worst case scenario, it is assumed that the release from carpet application occurs on 260 working days and to a middle size STP with an average daily flow of 115 ML (Brisbane Water, QSL). Assuming no removal of the notified polymer via adsorption to sludge in the STP, the resultant predicted environmental concentration in rivers (PEC_{river}) is calculated as 35.12 µg/L (PEC_{river} = 15000 kg/year × 7% ÷ 260 days ÷ 115 ML/day).

On average, the release to sewer from carpet cleaning has been estimated to be up to 50% over a carpet's life time. Carpet treatment is expected to keep occurring year after year on the same scale. As a worst case, the PEC in sewerage effluent from the annual release of the notified polymer from carpet cleaning has therefore been calculated assuming that up to 50% of the annual import volume will be released to sewer each year. Treated carpets are likely to be used across Australia and releases due to the cleaning of carpets in dispersed locations are expected to occur 365 days per year. Assuming no removal of the notified polymer in the STP, the predicted PEC_{river} is 4.54 µg/L if the daily polymer release (15,000 × 50% kg/365 = 20.55 kg) is diluted by the daily effluent production (200 L/person/day × 22.613 million people = 4,523 ML).

Based on the above calculations, the worst-case concentration for the notified polymer in rivers due to the combined release to STP from use and cleaning is 39.66 µg/L (= 35.12 µg/L + 4.54 µg/L). The worst case PEC is well below the EC50 (> 25 mg/L) for fish, daphnia and algae as reported above.

The notified polymer is not expected to cross biological membranes due to its high molecular weight and is therefore not expected to bioaccumulate. In landfill and water, the notified polymer is expected to ultimately degrade via biotic or abiotic pathways to form water, oxides of carbon and nitrogen and hydrogen fluoride. Therefore, based on the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.