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# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

## **FULL PUBLIC REPORT**

## Polymer in EFKA-4340

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## **FULL PUBLIC REPORT**

## Polymer in EFKA-4340

## 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Ciba Specialty Chemicals Pty Ltd (ABN 97 005 061 469)

235 Settlement Road

Thomastown VIC 3074

NOTIFICATION CATEGORY

Standard: Polymer with NAMW  $\geq 1000$  (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Identity

Purity

Identity And % Weight Of Hazardous Impurities

Identity And % Weight Of Non-Hazardous Impurities

Weight of Additives/Adjuvants

Import Volume

Identity of Customer Sites

Weight Percentage and Ingredients

Number-Average Molecular Weight

Residual Monomers/Other Reactants

Low Molecular Weight Polymer

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

**Melting Point** 

Boiling Point

Density

Vapour Pressure

Hydrolysis as a Function of pH

Partition Coefficient

Adsorption/Desorption

**Dissociation Constant** 

Particle Size

Flash Point

Flammability Limits

Autoignition Temperature

**Explosive Properties** 

Reactivity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Nο

NOTIFICATION IN OTHER COUNTRIES

Notifications have been submitted in USA, Canada, Japan and Korea during 2005.

## 2. IDENTITY OF CHEMICAL

OTHER NAME(S)

Acrylic block-copolymer

MARKETING NAME(S)

EFKA-4340 (product containing the notified polymer)

SPECTRAL DATA

METHOD Infrared spectroscopy and Gel Permeation Chromatography

Remarks Reference spectra were provided.

## 3. COMPOSITION

DEGREE OF PURITY

> 90%

#### **DEGRADATION PRODUCTS**

No degradation, decomposition or depolymerisation of the notified polymer is expected to occur under normal conditions of use.

Thermal decomposition may release toxic fumes containing mostly products of combustion such as carbon monoxide, carbon dioxide and oxides of nitrogen.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

No losses by volatilisation, exudation or leaching are expected from the notified polymer.

#### 4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS The notified polymer will be imported as 55% of EFKA-4340.

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

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

Use

Additive in solvent based automotive coatings.

## 5. PROCESS AND RELEASE INFORMATION

### 5.1. Distribution, transport and storage

PORT OF ENTRY Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS Ciba Specialty Chemicals Pty Ltd 235 Settlement Road Thomastown Vic 3074

#### TRANSPORTATION AND PACKAGING

EFKA-4340 containing the notified polymer will be imported by sea in 25 kg pails and 200 kg steel drums. The containers will be transported by road to a storage site, and then supplied to paint manufacturers in Australia, for formulation into a range of paints. The finished paints will be packaged in 1 L, 4 L and 10 L steel paint cans and 200 L drums. The paints will be distributed to end use sites within Australia.

## 5.2. Operation description

The notified polymer will not be manufactured in Australia, but will be imported as a 55% blend in 25 kg pail and 200 kg steel drums. EFKA-4340 containing the notified polymer will be transported to a warehouse for storage before it is sent to paint manufacturers for formulation into paint products. Truck drivers will transport the sealed EFKA-4340 containers by road from the wharf to the warehouse and

then as needed to the customer warehouse.

The polymer solution will be reformulated into paint products at the paint manufacturing sites. Formulation of the notified polymer into paint products or pre-mixes will involve transfer of notified polymer by metered dosing to mixing vessel and mixing polymer solution and other ingredients in a sealed vessel fitted with a high speed mixer and local exhaust ventilation. Each batch will be quality checked and adjustments made as required. The resultant paint will be filtered prior to being dispensed into 1 L, 4 L and 10 L steel paint cans and pails using automated filling machine under exhaust ventilation. Paint products containing the notified polymer will be warehoused at the notifier's site prior to distribution to customer sites.

At the end user sites the paint containing the notified polymer is used in the automotive industry, for both original equipment manufacture (OEM) and refinishing of components. At the customer sites the paint will be stirred and diluted, then placed in a spray apparatus. The object to be primed with the paint will be sprayed then heat cured, resulting in the painted article.

## 5.3. Occupational exposure

Number and Category of Workers

Category of Worker Transportation and Storage	Number 3	Exposure Duration 2-3 hours/day	Exposure Frequency 10-15 days/year
Transporting from dock to notifier's site for warehousing (loading/unloading			
trucks)			
Paint manufacture	6	30 min to 6 hrs/day	4 days/week
Workers involved in weighing, mixing			4 weeks/year
and bead milling operations.			
Workers involved in filling cans of	4	3 hrs/day	4 days/week for 4
coating			week working period
Quality control/chemists and technical	4-8	1 hr/day	4 days/week for 4
service		· · · · · · · · · · · · · · · · · · ·	week working period
Cleaning operations	2	30 min/day	4 days/week for 4
		·	week working period
Paint application			
Automotive industry	>1000	8 hrs/day	5 days/week

## Exposure Details

Transport and Storage

Waterfront, transport and warehouse workers are not expected to be exposed to the notified polymer except in the case of an accident involving spillage of the EFKA-4340 containing the notified polymer at 55% concentration.

#### Paint formulation

During paint formulation there is possible dermal and ocular exposure of workers to drips, spills and splashes of EFKA-4340 or formulated paint containing <10% of the notified polymer. Such exposure could occur during charging of the mixing tank, taking QC testing samples and when plant and equipment is cleaned or maintained. Engineering controls such as metered dosing and enclosed mixing tanks are expected to be in place to minimise dermal/ocular exposure. Personal protective equipment (PPE) is expected to be worn by workers during this process – coveralls, goggles and impervious gloves.

During filling of cans, possible dermal/ocular exposure to paint containing <10% of the notified polymer may result from drips and spills when connecting filling lines, or during equipment malfunction. Workers wear coveralls, goggles and impervious gloves.

Maintenance workers and laboratory staff may also encounter dermal/ocular exposure during equipment maintenance and testing processes. To minimise exposure, coveralls, goggles and gloves are worn.

Inhalation exposure during formulation or filling of paint is unlikely as aerosols are not expected to be formed and exhaust ventilation systems are in place to control exposure to other components of the paints.

## End-use of paints in spray painting

Workers exposed during end-use of the formulated paints will mostly consist of spray painters preparing and applying the formulated paint coatings to surfaces (e.g. automotive parts), and cleaning equipment after use. As the paints are to be used in both OEM and refinish operations, there could be variations in the scale and sophistication of the spray painting operations, and the controls in place that would affect exposure.

The final concentration of the notified polymer in paints will be < 10%, reducing the potential for worker exposure. Dermal exposure is possible during preparation of paint, which involves stirring, transfer and dilution steps. Aerosols may be formed during spray application and therefore inhalation exposure may be possible. To minimise exposure during end use, the paint is diluted and applied in a well ventilated, down draft spray booth with an effective fume extraction system. Workers also wear anti-static footwear and flame retardant overalls, impervious gloves, eye protection and an air fed breathing mask or respirator if local exhaust is inadequate.

Spray painting may be carried out without the full range of controls mentioned above, increasing exposure.

Worker exposure to the notified polymer in dried paints is likely to be minimal, as the polymer will be encapsulated as part of the cured paint film.

#### 5.4. Release

#### RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured in Australia. Local operations will include transport and storage, paint formulation, filling and packaging and application by end-users using spray gun.

During storage and paint manufacture the notified polymer will be released in the following ways:

Spills - up to 1%, up to 50 kg annually to landfill

Import container residue - less than 2%, up to 100 kg annually to waste contractor

Process equipment cleaning - up to 1%, up to 50 kg generally to next batch

During the paint formulation operations, it is anticipated that there will be minimal release of the notified polymer during manual transfer from the storage containers to the mixers and during filling of paint into containers or during blending since it is undertaken in enclosed systems under exhaust ventilation and in a bunded area. Spills will be within bunded areas and collected with inert absorbent material (eg sand) and placed in a sealable container ready for disposal. The process equipment, blending tanks and mixers, will be cleaned with suitable solvent which is collected and used in the next batch, if possible, otherwise it will be disposed off-site.

Import containers will be rinsed with the rinsate being used in the paint formulation and the rinsed containers will be disposed of off-site via licensed waste contractors.

## RELEASE OF CHEMICAL FROM USE

Release of the notified polymer to the environment as a result of its use in the automotive industry is expected to be minimal, unless an accidental spillage occurs, and include:

Spills - up to 1%, up to 50 kg annually to landfill

Container residue - up to 2.5 %, up to 125 kg annually to landfill

Overspray - up to 30%, up to 1500 kg annually to landfill

Equipment cleaning - up to 5%, up to 250 kg annually to waste contractor

All spills will be contained, collected with inert absorbent material (eg sand) and placed in a sealable container ready for disposal. Since the modern HVLP spray guns have a 70% spray efficiency while the older high pressure guns have an efficiency of only 30%, the former are used more frequently and have been used in the above overspray release estimation. As the paint will be applied within a specialised spray booth, all overspray will be contained and collected for disposal.

Any paint residue in empty paint containers will be allowed to dry and then disposed of with the container.

Painting equipment will generally be cleaned with solvent. This effluent will be collected and reused if possible otherwise it will be disposed of off-site.

## 5.5. Disposal

The rinsed import containers, 25 kg pails and 200 kg steel drums, and steel end-user paint cans, containing any residual notified polymer (up to 225 kg annually), will be disposed to landfill as industrial waste. At the paint manufacturing plants effluent generated during container rinsing and equipment cleaning effluent (up to 150 kg of waste notified polymer annually), will be collected and reused where possible. Otherwise it will be disposed of to a liquid waste facility by a licensed contractor (eg for solvent recovery). A further 250 kg will go to liquid waste contractors from the cleaning of paint application equipment. There will be no release to sewer.

Any spilt material (accounting for up to 100 kg annually of the notified polymer) will be is disposed of to landfill. The spray booth filters are replaced every 2 to 4 months and the used filters (containing up to 1500 kg of notified polymer annually) will be disposed of to landfill. Any effluent from wet scrubbers, if used, will go to licensed liquid water facilities.

#### 5.6. Public exposure

The general public is not expected to come into contact with EFKA-4340 or products containing it, except in the case of transport accidents where the packaging was breached.

Once the paint containing the notified polymer is applied to the substrate in the automotive industry, the notified polymer is bound in an insoluble polymeric matrix and is not bioavailable.

#### 6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa

Clear brownish viscous liquid (product containing the

notified polymer).

Melting Point -54 °C

Remarks Analogue chemical (n-butyl acrylate polymer)

**Boiling Point** 120°C at 101.3 kPa (solvent)

Remarks Method not specified – value taken from MSDS.

**Density**  $1000 \text{ kg/m}^3 \text{ at } 20^{\circ}\text{C (solvent)}$ 

Remarks Method not specified – value taken from MSDS.

**Vapour Pressure** 12 hPa at 20°C (solvent)

Remarks Method not specified – value taken from MSDS.

Water Solubility > 2 g/L at 20°C

METHOD OECD TG 120 Water Solubility Remarks Total organic carbon (TOC).

The result indicates that in the environment the notified chemical is readily water

soluble.

TEST FACILITY Polysis Lab (2005)

Hydrolysis as a Function of pH

A standard hydrolysis study was not conducted however a stability in water test at pH 1.2, 4, 7 and 9 was conducted.

Samples of the notified chemical were agitated in water at 40 °C at pH1.2 for 24 h and at pH 4, 7 and 9 for 336 h. After agitation, samples were analysed by GPC and FTIR to determine if there were any changes in molecular weight distribution or structure. The samples from pH 7 and 9 were separated by freeze drying. The findings indicate that there was a change in molecular weight distribution at pH 7 and 9. This indicates that a reaction/hydrolysis did occur at these pHs. It should be noted that agitation for 336 h is very long and the temperature was not representative of environmental temperature (20-25°C).

Therefore while the notified polymer does contain functional groups that have the potential to undergo hydrolysis it is not expected to occur in the environmental pH range 4-9 at normal environmental temperatures.

Partition Coefficient (n-octanol/water)

Not determined but it is expected to partition into the organic phase despite its water solubility.

Adsorption/Desorption

Not determined. Due to its cationic charge, it is expected to be immobile and adsorb to organic matter in soil.

**Dissociation Constant** 

Not determined

Remarks The notified polymer contains a tertiary nitrogen atom with pKa ranging from 9.0

- 11.0 (also contains a quaternary nitrogen atom).

Particle Size Not applicable as imported in solution.

Flash Point 35°C (solvent)

Remarks Method not specified – value taken from MSDS.

Flammability Limits Upper: 13.1% (solvent)

Lower: 1.9% (solvent)

Remarks Method not specified – value taken from MSDS.

**Autoignition Temperature** 270°C (solvent)

Remarks Method not specified – value taken from MSDS.

Explosive Properties Not explosive, however formation of explosive air vapour

mixtures is possible.

**Reactivity** Stable under normal conditions of use.

## 7. TOXICOLOGICAL INVESTIGATIONS

No toxicity data were submitted.

#### 8. ENVIRONMENT

#### 8.1. Environmental fate

No environmental fate data were submitted.

#### 8.2. Ecotoxicological investigations

No ecotoxicity data were submitted. The polymer is cationic with a MW>1000 and therefore is potentially a polymer of concern. The aquatic toxicity increases with charge density with the mode of action being surface activity (they react with biological membranes). Algae appear much more sensitive than fish to this type of polymer. With the potential for approximately 25% cationic functionality there may be significant aquatic toxicity.

#### 9. RISK ASSESSMENT

#### 9.1. Environment

#### 9.1.1. Environment – exposure assessment

Exposure will only occur due to use of the notified polymer as it will not be manufactured in Australia. It will be reformulated into paints that will be used across Australia by professional trades people in the automotive industries, ie will not be available for general consumer use. The proposed use pattern and waste management indicate a low potential for environmental release of the notified polymer. Solid wastes (containing up to 3450 kg annually of the notified polymer) resulting from the paint manufacture and paint use will be collected and sent to landfill or possibly to incineration.

Liquid effluents (containing up to up to 800 kg) produced from paint formulation and use will be collected by licensed liquid waste contractors for solvent recovery, where it is likely the notified polymer will end up in any resultant sludge which will be disposed of to landfill. A small amount of the notified polymer may be present in the final effluent discharged to sewer, which is expected to undergo further treatment prior to eventual discharge to the aquatic environment. The notified polymer has the potential to be cationic. Cationic polymers with a number average molecular weight greater than 1,000 are assumed to partition mainly to the solids phase and to be 90% removed relative to the total influent concentration. The remaining 10% is assumed to be discharged to receiving waters although much of this material is likely to be in the form of polymer sorbed to suspended solids (Boethling and Nabholz 1997).

Following application and curing, the notified polymer is likely to be tightly cross-linked within an inert matrix. Due to its large molecular weight, the potential for bioaccumulation is very low.

#### 9.1.2. Environment – effects assessment

No ecotoxicological data were provided for the notified polymer, thus a PNEC cannot be estimated. Following application and curing, the notified polymer will be within an inert matrix and be unavailable to organisms. However, being cationic any unbound polymer is likely to exhibit significant toxicity to aquatic organisms, particularly algae (Boethling and Nabholz 1997).

#### 9.1.3. Environment – risk characterisation

The notified polymer will interact with other components to form a stable chemical matrix and, once dry, is expected to be immobile and pose little risk to the environment. After the useful life of painted article, the notified polymer will suffer the same fate as the article. If the article is recycled then the notified polymer will be destroyed during the heating process to release water vapour, oxides of carbon and nitrogen and hydrogen chloride.

Within a landfill environment, the notified polymer contained in waste from paint manufacture and paint application, including cured paint, will be immobile and is expected to breakdown at a very slow rate by biotic and abiotic processes.

The notified polymer is not likely to present a hazard to the environment when it is stored, transported, used, recycled and disposed of in the proposed manner.

#### 9.2. Human health

#### 9.2.1. Occupational health and safety – exposure assessment

During transport and storage, worker exposure to EFKA-4340 containing the notified polymer or to products containing it, is expected to be very low, and would only occur if accidental spillage of the materials occurred.

During processing of EFKA-4340 into paint formulations there is potential for dermal/ocular exposure of workers. However standard engineering controls for formulation, eg enclosure and local exhaust ventilation, would limit this to incidental exposure. Exposure at this stage could occur to EFKA-4340 containing 55% of the notified polymer, or to paint formulations containing < 10% of the notified polymer.

Potential for exposure occurs at the end-use stage, when paint formulations containing < 10% of the notified polymer are prepared for application and sprayed onto automotive components. Dermal/ocular exposure is likely during cleaning of the equipment and during the small-scale preparation for spraying, which may involve stirring the paint, diluting with solvent, and transfer to the spray gun. During the spraying process itself, inhalation and possibly ingestion exposure is possible, because aerosols containing the notified polymer would be formed during atomisation of the paint. The extent of dermal/ocular and inhalation exposure will depend on the controls in place, including isolation and engineering measures. It is estimated that > 1000 workers will carry out spray painting using formulations containing the notified polymer. Some of this will occur at large facilities manufacturing new automotive components. Some will occur as refinishing at crash repairer shops which may vary in the type and effectiveness of spray booths or other equipment. While much of the spray painting may be carried out with a high level of controls, the possibility of less effective control measures and therefore higher worker exposure cannot be ruled out.

It should be noted that worker exposure to the notified polymer in paint would leave obvious staining, and would therefore be avoided by workers wherever possible.

Worker exposure to the notified polymer in dried paints is likely to be minimal, as the polymer will be encapsulated as part of the cured paint film.

## 9.2.2. Public health – exposure assessment

Once the paint containing the notified polymer is applied to the substrate in the automotive industry, the notified polymer is bound in an insoluble polymeric matrix and is not bioavailable. Therefore no significant dermal or inhalation exposure to the public is expected.

## 9.2.3. Human health – effects assessment

The high molecular weight of the notified polymer and low level of species of molecular weight < 1000 should preclude absorption across biological membranes, and systemic toxicity is not expected. As no toxicological data have been submitted the notified polymer cannot be classified under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

However the notified polymer contains a residual monomer that is a skin sensitiser. This monomer is present in the commercial product EFKA-4340 at a significant level, but below the cut-off level for classification under HSIS (2006).

Therefore EFKA-4340 containing the notified polymer may produce sensitisation on skin contact.

## 9.2.4. Occupational health and safety - risk characterisation

The health effects of the notified polymer have not been characterised. Its absorption into the body is expected to be low because of its high molecular weight. However it may have skin sensitising effects because it contains a significant level of a residual monomer that is a skin sensitiser. The level of this monomer present is lower than the cut-off concentration for classification under HSIS (2006).

During formulation exposure would be reduced by engineering controls such as enclosed tanks, but some risk of skin sensitisation remains through incidental skin contact with EFKA-4340 or paint containing the notified polymer. This risk would be further reduced by use of protective clothing including gloves.

In spray painting both engineering controls such as spray booths and full personal protective equipment are needed to reduce the exposure and the risk of skin sensitisation to acceptable levels. The risk would be further reduced by spray painting being carried out according to the NOHSC *National Guidance Material for Spray Painting* (NOHSC, 1999b).

Overall the health risk to workers is considered low, if appropriate engineering controls are in place to prevent exposure.

#### 9.2.5. Public health – risk characterisation

Once the paint containing the notified polymer is applied to the substrate in the automotive industry, the notified polymer is bound in an insoluble polymeric matrix and is not bioavailable. Therefore no significant exposure to the public is expected.

## 10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

## 10.1. Hazard classification

Based on the available data the notified chemical cannot be classified as a hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

As a comparison only, the classification of notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

Based on available data it is not possible to categorise the notified polymer according to the GHS for either health or environmental effects..

## 10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

## 10.3. Human health risk assessment

## 10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

## 10.3.2. Public health

There is Negligible Concern to public health when used as an ingredient of automotive paints.

#### 11. MATERIAL SAFETY DATA SHEET

#### 11.1. Material Safety Data Sheet

The MSDS of product containing the notified chemical provided by the notifier was assessed in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant. One revision is recommended to the MSDS of EFKA-4340.

#### 11.2. Label

The label for the product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

#### 12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following isolation and engineering controls to minimise occupational exposure to the notified polymer:
  - Closed tanks and lines for formulation and filling of paint containing the notified polymer;
  - Use of engineering controls in spray painting to minimise exposure of workers.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer;
  - Avoid splashing, spills and generation of aerosols during formulation and filling processes;
  - Spray application of paint containing the notified polymer should be in accordance with the NOHSC *National Guidance Material for Spray Painting* (NOHSC, 1999)
  - Workers using spray products containing the notified polymer should be instructed in their proper handling and use, including information about the additional risks posed by spray application.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Protective gloves
  - Safety glasses or goggles
  - Industrial clothing
  - Respiratory protection during spray painting, or if aerosols are formed
  - Full body protection during spray painting
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

#### MSDS

The MSDS for EFKA-4340 containing the notified polymer should be altered to include information on possible health effects from a residual monomer that is a skin sensitiser. It is recommended that the Acute Health Effects –Skin section of the MSDS include the statement "May cause sensitisation by skin contact as low levels of

a sensitising chemical are present".

#### Environment

- The following control measures should be implemented by paint manufactures and warehouse sites to minimise environmental exposure during paint formulation and storage of the notified chemical:
  - All process equipment and storage areas should be bunded.

## Disposal

 The notified polymer should be disposed of to landfill for solids and to licensed waste contractors for liquids.

## Emergency procedures

- Spills or accidental release of the notified polymer should be contained by soaking up
  with inert absorbent material and dispose of as special waste in compliance with local
  and State regulations as recommended in the MSDS.
- Use detergent in cleaning up.
- Prevent product from entering drains.

#### 12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
  - Due to the potential cationic nature of the notified polymer, if there are any changes to the use pattern whereby significantly increasing the potential of aquatic exposure. If this occurs, full ecotoxicity studies for fish, daphnia and algae may need to be submitted to NICNAS for assessment.

or

- (2) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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