File No PLC/669

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Sekisui Techpolymer MBX series

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Director
NICNAS

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FULL PUBLIC REPORT

Sekisui Techpolymer MBX series

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Cintox Pty Ltd (ABN 85 096 197 885)
121 Carlton Crescent
Summer Hill NSW 2130

NOTIFICATION CATEGORY
Polymer of Low Concern

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, Use Details, Manufacture/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
None. The notified polymer is listed on the TSCA, EINECS, ECL and ENCS inventories.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sekisui Techpolymer MBX series

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >10,000 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 White powder
Melting Point/Glass Transition Temp >250ºC
Density ~1,200 kg/m^3
Water Solubility Expected to be insoluble based on the lack of polar functionality and expected level of cross-linking.
Particle Size Several grades of the notified polymer will potentially be imported, with a range of particle sizes.

Grade	Mean particle size (µm)	Diameter at 25% (µm)	Diameter at 75% (µm)	% respirable <10 µm	% inhalable <100 µm
MBX-5	5.261	3.833	6.342	97.6	100
MBX-8	6.684	5.015	8.023	92.2	100
MBX-12	11.62	8.677	14.05	61.4	100
MBX-20	17.01	12.53	20.97	13.3	100
MBX-30	28.12	22.31	34.08	1.5	100
MBX-50	48.02	37.55	58.49	0.1	~99.9

Reactivity Stable under normal conditions of use.
Degradation Products None under normal conditions of use. While the notified polymer may hydrolyse, this is not expected to occur within the environmental pH range of 4-9.

5. INTRODUCTION AND USE INFORMATION

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

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

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The powdered notified polymer will be imported through Sydney in 20 kg paper bags (inner is laminated with polyethylene).

Reformulation/manufacture processes

The notified polymer will be reformulated into paint, ink or plastic master batch pellets for plastic sheet manufacture. Note that customers for the notified polymer have not been confirmed, and the sites of reformulation and/or use are not known. The processes described below are thus considered only to be those that can be anticipated.

The manufacturing process is essentially the same for both paint or ink products, and will involve opening of the bags, pouring into a hopper, blending, filling and packaging operations. Workers will cut open the bags containing the notified polymer and manually pour the powder into a hopper. The required amount of notified polymer is automatically dosed into an enclosed blending tank. After blend with other ingredients is completed, a QA sample is taken by a laboratory technician via a sampling port. The finished paint or ink is then pumped to an enclosed filling machine. The finished product is filled into 1 L to 20 L metal cans, which are closed within the machine. These are automatically packaged on palettes for distribution to end-users.

For the manufacture of plastic masterbatch pellets, the lined paper bags are expected to be manually cut open and emptied into a hopper, which feeds into a mixer. The production process is expected to be otherwise automated: controlled and monitored remotely by an operator. The mixer is sealed during mixing. After mixing, the mixer opens directly into the extruder below, through a sealed tube. In the extruder, the raw materials are melted and mixed: a continuous process (200-300 kg/hour) that operates at 200ºC. The melted mixture will be extruded through die holes in long spaghetti-like strings, which will pass through a cooling water bath into a pelletiser and classifier. This will cut the strings into pellets (approximately 5 mm width), which will be graded and conveyed to a hopper for automatic filling and sealing into plastic bags. Workers will load the bags onto pallets for storage and transport.

The master batch will be distributed to extruding companies to be used in the production of plastic articles.

The manufacture of plastic sheets will be an injection-moulding process. The master batch pellets will be either transferred by vacuum or manually tipped by the operator into the feeding hopper on the injection-moulding machine. The mixed pellets will be fed into the barrel of the machine by gravity. Once heated, the melted pellets will be moulded into a plastic film, which is collected on a roller. The sheet will be unrolled and automatically cut into the desired shape, then coated onto the substrate.

Use

The notified polymer will be used as an additive in paint, ink and plastic articles, to alter their light scattering and reflective characteristics. The approximate proportion of the import volume of the notified polymer that will be used in these different application areas will be 30%, 30% and 40%, respectively. The concentration of the notified polymer in end-use products will be <10%.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (Hours/Day)*	*Exposure Frequency (Days/Year)*
Transport and storage	10-20	4-8	200
Manufacturing operators	200	8	200
QA	10	1	200
Maintenance workers	10	1	200
Paint and ink applicators	>1000 (~1-10/site)	8	200
Extrusion workers	50-100	8	200

OCCUPATIONAL EXPOSURE

Customers for the notified polymer have not been confirmed, and the sites of reformulation and/or use are not known. The notified occupational exposure scenarios are thus considered the expected situations only.

Transport and warehousing

Transport workers should not be exposed to the imported notified polymer, as they will be handling closed containers. Exposure would only be possible in the event of an accident where the packaging is breached.

Paint, ink and plastic masterbatch reformulation

Dermal and ocular exposure are possible, but exposure to significant amounts of the notified polymer is limited because of the use of the following personal protective equipment:

- All manufacturing and maintenance personnel are expected to wear overalls, safety boots, safety glasses, hardhat and impervious gloves.
- Maintenance workers will be involved in routine maintenance and troubleshooting. The processing line is stopped and flushed out before any maintenance work is commenced.
- QA staff are expected to wear a laboratory coat, safety glasses and impervious gloves.

Inhalation exposure is also possible as the notified polymer is an inhalable powder until it is formulated into liquid products.

- Workers who will be involved in cutting bags and pouring the notified polymer in powder form are expected to wear a dust musk or a respirator. Also, the area is proposed to be supplied with local and general ventilation. The number of workers that will handle powders will be 1-2 per site.
- The blending, filling and packaging processes are also expected to be supplied with local ventilation.

Other routes of exposure are unlikely to be significant during manufacturing processes.

After reformulation, workers will possibly make dermal contact with masterbatch pellets, dried ink or dried paint containing the notified polymer. However, the notified polymer is cured into an inert matrix

and is hence unavailable to cause exposure.

Paint and ink end-users

Dermal and inhalation exposure is possible during the use of paints and inks containing the notified polymer. Paint and ink applicators will apply these products using brush, roller or by spraying. Workers exposed to the reformulated product would mostly consist of professional painters.

- Spray painting is proposed to be conducted in ventilated spray booths that are equipped with recirculating systems, where inhalation, dermal and ocular exposure is expected to be minimal.
- The spray operators are expected to wear anti-static flame retardant overalls, anti-static footwear and cartridge type respirators.

Plastic extrusion

During and after extrusion into plastic articles, the notified polymer will be encapsulated and physically contained within the material. Thus, no exposure to the notified polymer is anticipated.

The extrusion process is supplied with local ventilation. Workers are expected to wear protective clothing, safety glasses, and a hard hat.

PUBLIC EXPOSURE

The notified polymer will not be sold to the public. Powders of the notified polymer will only be used in industry, and as such, public exposure is not expected. The public may be exposed in the unlikely event of a transport accident where the transport containers are breached and product is spilled.

The public will also be exposed to surfaces coated with the paint or ink containing the notified polymer. Members of the public may also be exposed to plastic film containing the notified polymer. In these types of surfaces, the notified polymer will be bound within a cured or set polymer matrix and will not be available for exposure. Blooming/leeching of the notified polymer from the articles is not expected and any potential exposure will thus be low.

6.2. Toxicological Hazard Characterisation

No toxicology data have been provided for the notified polymer, but as it is notified under the PLC criteria, it can be considered to be of low hazard. The notified polymer is likely to be not bioavailable and non-toxic, due to its probable very high molecular weight, cross-linking and water insolubility. The main risk of adverse health effects presented by the notified polymer is from its small particle size.

The particular grades (and thus, particles sizes) of the notified polymer that are to be imported are uncertain. Mean particle sizes of 5 µm to 50 µm are likely. These particles are described as "*spherical microparticles with minimal aggregation... Flowable, dispersive, and slippery, all at high levels*" (http://www.syntheticspecialties.com). The ability of these particles to form airborne dusts is unknown, although this characteristic might be restricted by the aerodynamic character of the particles.

The notified polymer is comprised primarily of inhalable particle sizes (<100 µm), with most grades containing smaller particle sizes in the respirable range (<10 µm). The health effects of inhalation exposure to the notified polymer are unknown. The notified polymer is unlikely to be absorbed from the lung, so deposition in the deep lung is probable, combined with an inability of the lungs to dislodge the particles. Inhaled particulates are known to interfere with cell function in the airways, causing inflammatory-like reactions[*]. Therefore, bronchial or pulmonary irritation is possible following inhalation exposure to particles containing the notified polymer, arising from deposition of water-insoluble particles in the lung. The US EPA have similarly expressed concern regarding high molecular weight (70,000 Da or greater) insoluble polymer particles of respirable size, as they can potentially result in irreversible lung damage.

In addition, the notified polymer may also be formulated into porous spherical particles. Porous cross-linked polymers with the same composition as the notified polymer swell directly in water and can absorb ~2 mL water/g polymer[**]. Water-swellable polymer particles of respirable size are a potential health concern, because of data from a 2-year chronic inhalation rat study for a water-absorbing polyacrylate polymer, where lung tumours were observed following exposure to 0.2-0.8 mg/m^3. The inhalation of water absorbing polymers may cause lung damage, as the lungs are unable to clear the inhaled particles. It is for this reason that water absorbing polymers with NAMW >10,000 Da cannot be PLCs. Based on this, the formulation of the notified polymer into porous particles is believed to present a significant risk to human health in the absence of relevant toxicological data.

[*] R.C. Rylander (1997) Organic dusts. In: Roth RA, ed. *Comprehensive Toxicology, Volume 8: Toxicology of the Resipratory System*. Elsevier Science Ltd., pp 415-424.

[**] X Wang, J Yan, C Zhou. (2000). Journal of Applied Polymer Science, Vol. 78, 250–258.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

The notified polymer meets the PLC criteria. Thus, it is expected to be generally a low health hazard to workers, following oral, dermal or ocular exposure, except when formulated into porous particles. Any intention to import porous particles requires that the Director be notified, so that consideration can be given to a secondary notification (see Section 10.1).

The workers who will be potentially exposed to powders of the notified polymer are mainly **reformulation operators**, and these workers face the greatest potential risk of adverse health effects arising from exposure to the notified polymer. Of main concern to the health of workers is the risk from inhalation exposure to the notified polymer, due to the potential adverse health effects of respirable insoluble particulates. Inhalation exposure to the notified polymer could occur during opening of the lined paper bags containing the notified polymer and manually transferring the contents to a hopper. When the amount of handling and the import volume is taken into account, a medium risk to worker safety is presented from the notified polymer.

The EASE model predicts maximal atmospheric particulate concentrations of 2-5 mg/m^3 during weighing and addition of powder to the mixer, but actual levels are likely to be lower where dust control measures are used (<1 mg/m^3). The Australian recommended exposure standard for nuisance dust is 10 mg/m^3 [NOHSC 3008:(1995)], but a recommended exposure limit of 3 mg/m^3 has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for

"respirable (insoluble) particulates (not otherwise regulated)".

Appropriate control measures to mitigate inhalation exposure to respirable particles of the notified polymer should be implemented. Such controls include an approved dust respirator and/or appropriate engineering controls (eg local exhaust ventilation) where airborne dusts of the notified polymer are concentrated. Dust masks have been proposed, which may be sufficient protection against dusts containing the notified polymer when weighing out and adding powder to a mixer, and would be especially important to mitigate the effects of large accidental spills involving dust generation (such as accidental spillage of the contents of a bag containing the notified polymer).

The use of dust masks, in combination with adequate general ventilation and local exhaust ventilation, will reduce the risk to reformulation workers' health. With these measures in place, high dust levels are unlikely to be reached in the workplace, and there is a low risk of adverse acute or chronic lung conditions either arising or being aggravated in exposed workers.

Paint and ink end-users will apply these products by brush, roller or spraying. Workers exposed to the reformulated product would mostly consist of professional painters. Dermal and inhalation exposure is possible during the use of paints and inks containing the notified polymer. The highest-risk exposure to products containing the notified polymer will arise where spray application is used. However, the risk presented by this kind of application is lower, as the particles are suspended in droplets of paint or ink. Generally, paint and ink workers are likely to be trained in the spray application of paints that contain solvents of much greater hazard than the notified polymer, and wear appropriate PPE. In addition, much of this kind of work is likely to be conducted in ventilated spray booths, which would reduce any potential inhalation, dermal and ocular exposure to the notified polymer.

Other categories of workers will only be exposed to the notified polymer bound within a plastic matrix (eg the master batch pellets or plastic articles), and therefore experience a negligible risk. Likewise, a negligible risk also applies to end-users of plastic articles containing the notified polymer.

PUBLIC HEALTH

The notified polymer will not be sold directly to the public, but will likely be present in products that are marketed to the public. The public will be potentially exposed to the notified polymer within manufactured plastic articles, or from dried ink or paint. However, in these states, particles of the notified polymer will be bound within an inert matrix and unavailable to cause any risk to public health. If the particles of the notified polymer were liberated (eg from inks on printed paper), they would not be present at sufficient concentrations to cause significant harm by inhalation. Therefore, the introduction of the notified polymer is unlikely to present any risk to public health for the notified uses.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

During Manufacturing

The notified polymer will not be manufactured in Australia. It will be imported as a raw material and will be formulated into paint and ink products locally. The polymer will also be used as an additive in the production of plastic masterbatch pellets which will undergo extrusion to produce plastic film.

Release to the environment could occur as a result of residues remaining in the lined plastic bags. This is estimated to account for 0.1% of the annual import volume. This total is for all three application areas. This will be disposed of to landfill along with the paper bag.

Release could also occur as a result of accidental spills. This is estimated to be up to 0.5% of the annual import volume. Spills will be collected using an industrial vacuum cleaner and the collected waste will be placed in suitable robust containers and will be disposed of to landfill.

The processing equipment used in the manufacture of paint or ink will be cleaned by flushing with a suitable solvent. The solvent will be collected and reused in the manufacturing process. No material will be released to sewer.

Spilt paint or ink containing the notified polymer will be collected using a suitable adsorbent material and will be placed in a closed container for disposal to landfill. This is expected to account for 0.1% of

the annual import volume.

During masterbatch production, wastes are recycled back into the process. If the material is contaminated and unsuitable for recycling, it is collected and sent to landfill for disposal. The release to landfill from these wastes is expected to be 0.5% of the annual import volume.

During End-use

Any waste from the extrusion of the film will be disposed of to landfill. Wastes during extrusion are expected to constitute 0.5% of the annual import volume.

The paint will be applied by brush, roller or by spraying. A loss of 30% of the ready-for-use material due to overspray can occur with the use of HVLP spray guns and slightly higher loss with more outdated high-pressure guns. The engineering controls for over-spray are typically spray booth filters and water scrubbers. The spray booth filters are usually renewed every 2-4 months. The filters are disposed of to landfill, as are the scrubber waters. As a worst case, it is assumed that the resultant wastes from the application of paint will account for 30% of the annual import volume. Brushes, rollers and spray equipment will be cleaned with a suitable solvent. The washing will be collected and disposed of to landfill or incinerated. The loss from cleaning is expected to account for 1% of the annual import volume. Residue in containers will make up a further 0.5% of the annual import volume and this will be disposed of to landfill with the container.

The release to the environment from the use in ink products will occur from residues in containers (0.2% of the annual import volume) and from cleaning of equipment (0.6% of the annual import volume). The ink is likely to be printed onto substrates such paper or plastics using an automated process. The loss during printing is expected to account for 0.3% of the annual import volume.

At the end of the useful life of the finished articles containing the notified polymer, it is expected that the articles will be disposed of to landfill.

ENVIRONMENTAL FATE

There are no data for the biodegradation of the notified polymer and it is expected to only degrade slowly once released into the environment.

The notified polymer has a relatively high molecular weight and is cross-linked. Thus, it is expected to have negligible solubility in water. It is expected to bind strongly to sludge or organic matter in soil and is therefore, expected to be relatively immobile in the environment.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted.

The notified polymer meets the PLC criteria and is therefore expected to be of low environmental hazard. PLCs without significant ionic functionality are of low concern to the aquatic environment. In addition, the relatively high molecular weight indicates that the polymer is unlikely to cross biological membranes and bioconcentrate.

7.3. Environmental Risk Assessment

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

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

The notified polymer is not considered to pose a risk to occupational health and safety under the conditions of the occupational settings described.

8.2. Level of Concern for Public Health

There is Negligible Concern to public health when used in the proposed manner.

8.3. Level of Concern for the Environment

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

9. MATERIAL SAFETY DATA SHEET

9.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

10. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to powders containing the notified polymer during handling:
  - *Local exhaust ventilation and adequate general ventilation should be applied at sites where powders are handled.*

- Employers should implement the following safe work practices to minimise occupational exposure during the handling of powders containing the notified polymer:
  - *Avoid the formation of airborne dusts.*

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to powders containing the notified polymer:
  - *safety glasses, gloves and overalls.*
  - *dust mask (adequate for respirable particle sizes).*

- 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 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.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills/release of powders containing the notified polymer should be collected by vacuum and bagged or placed in a sealed container.

- Spills/release of plastic pellets containing the notified polymer should be collected with a broom and bagged.

10.1. 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 subsection 64(1) of the Act; if

- The notified polymer is introduced in a chemical form that does not meet the PLC criteria.
- The notified polymer is proposed for introduction in the form of porous particles, where any proportion of the particle size is of respirable diameters (<10 μm).
- The workplace environment (including the use of protective equipment) where respirable powders of the notified polymer will be handled differs significantly to the conditions described in the notification statement.
- The notified polymer is intended for use in a product for cosmetic or personal use.

or

(2) Under subsection 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.