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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION

AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in MIEX™

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polymer in MIEX™

1. APPLICANT

ICI Australia (Operations) Pty Ltd of 1 Nicholson Street MELBOURNE VIC 3000 has submitted a limited notification statement in support of their application for an assessment certificate for Polymer in MIEX™.

2. IDENTITY OF THE CHEMICAL

The notified polymer is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the polymer composition have been exempted from publication in the Full Public Report and the Summary Report.

Trade Name:	MIEX™ (Product)
Molecular Weight:	> 2.0 x 10^{10}
Maximum Percentage of Low Molecular Weight Species:	none detected
Spectral Data:	IR reflectance techniques

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	the notified polymer will be supplied as a brown aqueous slurry; when dried it is an odourless brown powder
Melting Point:	> 350°C (measured), partial decomposition occurs above 280°C
Specific Gravity:	not measured as the notified polymer is never manufactured in its pure form; calculated density of 1.26 g cm^{-3}
Vapour Pressure:	not measured as the notified polymer is a solid

	with a high molecular weight and melting point
Water Solubility:	not measured by standard techniques; estimated by non-standard techniques as 0.35μg per litre
Partition Co-efficient (n-octanol/water):	not measured due to the notified polymers insolubility in both water and organic solvents
Hydrolysis as a Function of pH:	the notified polymer is insoluble in water, but hydrolyses slowly at neutral pH
Adsorption/Desorption:	not measured, the notified polymer is insoluble in water and is not expected to migrate or adsorb in soils; due to its particulate nature it may migrate short distances in air
Dissociation Constant:	not measured as the notified polymer is insoluble in water
Flash Point:	not measured; as the notified polymer will be supplied as a product in slurry water
Flammability Limits:	not measured; the notified polymer will only be supplied as a product in slurry water; however the polymer when dry will burn releasing oxides of carbon and hydrogen chloride
Autoignition Temperature:	not measured; the notified polymer will only be supplied as a product in slurry water
Explosive Properties:	not measured; the notified polymer is stable and will not deteriorate as a result of heat, shock or friction
Reactivity/Stability:	the notified polymer is stable; may react with strong oxidising agents

Comments on Physico-Chemical Properties

The notifier claims that water solubility for the polymer was not able to be measured using conventional guidelines, eg column elution. A different approach was employed, where a single MIEX^{TM} bead was placed on a magnetic flea, its size measured, added to 5 litres of distilled water and stirred for 17 hours. The magnetic flea was then dried at 70°C for two hours, after which it was smaller than the original size. Although this decrease in size is believed by the notifier to be due to reasons other than solubility (the original bead contained water which was lost on drying), if it was due to dissolution, the measured solubility following this method is implied to be 0.35 μg/L.

Because of the polymer's insolubility in water and organic solvents, partition

coefficient was not measured. While not expected to migrate through soil, the polymer does have a particulate nature (dust), and the notifier expects it could migrate short distances due to wind.

The notified polymer will be supplied as the product MIEX™ in slurry waters therefore measurements have not been made for flammability limits, flashpoint, and autoignition temperature, which is acceptable.

4. PURITY OF THE CHEMICAL

The dried product comprises 75% polymer, 25% iron oxide. MIEX™ will be delivered as a slurry containing 70% product solids and 30% water (referred to as product water).

Toxic or Hazardous Impurities:	the water in which MIEX™ (containing the notified polymer) is supplied and an organic extract of the dried, crushed MIEX™ beads have been analysed to determine the impurities present; some of the impurities are potentially hazardous (1) and have exposure standards assigned (6), however as they are present at such low percentages, and the plant will be fully automated there is minimal concern for exposure to raw materials and impurities during the manufacture process
Additives/Adjuvants:	the product MIEX™ will contain a number of additives/adjuvants in addition to the notified polymer; some additives/adjuvants are used during product manufacture and are removed by vacuum, consumed or removed during the reaction process

5. USE, VOLUME AND FORMULATION

The notified polymer will be manufactured as MIEX™ product, in a brown aqueous media. The notified polymer is never isolated in the pure state. MIEX™ is an ion exchange resin that will be used to remove naturally occurring dissolved organic carbon (DOC) from surface water prior to disinfection, for use as potable (drinking) water.

The removal of DOC, largely humic and fulvic acids, has been one of the primary objectives of the water supply authorities in the treatment of water for potable purposes. DOC are produced from the decay of vegetable and animal materials, upon disinfection the presence of DOC allows formation of various carcinogenic disinfection by-products, which in recent years have been the subject of concern for public health.

The use of ion exchange resins for the removal of DOC is not new but the MIEX™ resin bead contains a magnetic component which affords better settling characteristics than non magnetic resins. The use of the MIEX™ resin therefore allows a resin based water treatment process to be operated in continuous flow through mode; thus providing a cheaper and more efficient process than conventional batch treatment processes.

Estimated manufacture is 10 to 100 tonnes in the first two years increasing to 100 to 1 000 tonnes in the following three years.

6. OCCUPATIONAL EXPOSURE

The product will be manufactured in Australia by ICI Australia in Victoria. Raw material ingredients, including the monomers that form the notified chemical, will be weighed under exhaust ventilation and transferred to a closed mixing vessel to minimise potential exposure. The blend will be piped automatically to the closed reaction vessel. The manufacturing plant will be automated with controls external to the reaction area negating the necessity for occupational exposure at any time during manufacture. Normal plant operations will be three, 8 hour shifts, 5 days per week. Product manufacture will be in a batch process with one batch being made per day.

During manufacture there is potential for worker exposure when handling raw materials, maintaining equipment, packing, cleaning or replacing wash water filters. It is estimated that 20 workers may be potentially exposed for up to one hour per day, 100 days per year, in conducting these processes. The product will be packed into 1 cubic metre intermediate bulk containers (IBC) with plastic liners by gravimetric means. There is the potential for exposure when workers are coupling or uncoupling the filling nozzle to the neck of the liner. IBC containing the product will be moved by forklift truck to a warehouse for storage. This same method is used to load and unload delivery trucks.

Approximately 50 to 100 workers may be potentially exposed to the product in water treatment plants during transfer from IBC to the addition tank. The MIEX is pumped from each IBC into the addition tank, therefore there is the potential for exposure to MIEX™ when inserting or removing the pump lance. IBC are moved from the warehouse to the addition tank by forklift. Treatment plants operate 24 hours per day, 365 days per year with operators working 8 hour shifts.

The most likely route of exposure during manufacture and use is dermal.

As the polymer is not volatile and is supplied as an aqueous slurry, atmospheric monitoring is not required, however the notifier states that personal monitoring will be performed on workers exposed to volatile organic compounds during manufacture.

If the slurry is allowed to dry out, for example following a spill on the floor, dust may form. There is also the potential for exposure to dried product (dust) during maintenance. The dust is unlikely to cause concern for inhalational exposure as the particle size is not in the respirable range but exposure as with all dusts should be

minimised.

7. PUBLIC EXPOSURE

On the information provided by the notifier public exposure to the notified polymer is not expected to occur. During the MIEX™ water treatment process losses of MIEX™ can occur from the settling stage, where it is estimated that up to 0.1% of the resin may be carried over with the clear water to the final filtration stage. However, MIEX™ will not be present in drinking water as it will be removed during the final water treatment filtration stage. Although the notifier has not provided estimates of the levels of impurities expected to be present in drinking water, MIEX™ will be used at a rate of 2-10 mL/L of water. Hence impurity levels in drinking water will be significantly reduced compared to those in the product water. Given the low levels of impurities expected to occur in drinking water, they are not expected to present toxicological hazards.

8. ENVIRONMENTAL EXPOSURE

Release

Manufacture:
The product will be manufactured at the ICI Specialty Chemicals plant at Deer Park, Victoria. Product manufacture will be a batch process with one batch being made per day. The product will be packed into 1 cubic metre IBC with plastic liners. When filled, IBC will weigh approximately one tonne.

The manufacture of MIEX™ is a conventional suspension polymerisation process where the reactants are added in a reactor vessel, during which polymerisation occurs. The resulted resin beads are aminated and magnetised. The washed product is packed in IBC and sent to the warehouse.

Release during product manufacture can occur during packing, cleaning and replacing wash water filters. Currently, the notifier's pilot plant has a loss of resin as "fines" of about 8% of the resin produced. The product fines are a result of mechanical breakdown of the parent molecules. While the full molecules have a mean size of around 100 µm, the fines may be around 5 to 10 µm. Their chemistry is unaltered. Although full scale production is likely to be more efficient, a worst case loss of 8% will see a maximum of 80 tonnes of fines produced per annum. These are trapped by filters, and will be disposed of to landfill. There may be some carry over of fines in wash water at product maturity, but these are expected to be filtered out during the water recycling process.

Other release can come from spills occurring in coupling and uncoupling the filling nozzle during packing operations. The notifier estimates this will be small (less than 100 kg per annum), and will be dealt with by normal housekeeping operations. In the event of a complete batch failure, disposal of up to 8 tonnes would be necessary, in which case, a licensed waste contractor would landfill the waste.

Water Treatment:
Water treatment plants operate 24 hours per day, 365 days per year. Incoming raw water is washed over the MIEX™ resin to remove dissolved organic carbon. Water containing the MIEX™ bead is released to a settling tank, where the resin is collected from the bottom of the tank and reused. Some fines may carry over from the settling tank, and these are removed through final filtration and form part of the sludge from the waste water treatment plant. Up to 40 kg of MIEX/day for a 50 ML treatment plant is released this way, and the sludge is either landfilled or released to sewer. Exposure through end use will occur predominantly through landfill, either of sludge from the treatment of raw water, or further down the line, with sludge from the sewage treatment plant. While some exposure to the aquatic system is possible, the use of the chemical in the treatment of potable water only makes this unlikely.
While potable water may be used for activities other than drinking (eg irrigation of gardens and ovals), exposure of MIEX™ through these routes is unlikely, as the notifier states all fines will be removed during the final filtration stage, leaving no notified chemical in the water after treatment.

Release of the polymer's hydrolysis product, will occur to sewer as this chemical is soluble in water. As noted above, testing showed that in product water, 65 days after manufacture, 180 mg/L of hydrolysis product (around 2.8 mg/L per day) was present. This rate of hydrolysis equates to around 33.6 mg of hydrolysis product (from 40 kg per day MIEX™) being present in sludge at each treatment plant, which will then be disposed of to sewer or landfill.

Fate

The majority of MIEX™ beads released either through accidental spills or as product fines will be landfilled. Here, it is expected to remain immobile within soil, although, due to its particulate nature, could be distributed small distances due to wind if it is present on the surface. MIEX™ is insoluble in water, but the ester linkages do hydrolyse slowly releasing one product.

The product of hydrolysis will partition to water with an estimated water solubility of 5.12×10^9 mg/L. It is unlikely to bioaccumulate as the calculated octanol water coefficient is -3 and the calculated bioconcentration factor is 1 (7).
Under aerobic conditions the half life of this product is estimated to range between 3 and 17 days, and hydrolysis is not expected to be an important transformation mechanism (7).

Bioaccumulation of the polymer is not expected because of its very high molecular weight, which is likely to inhibit membrane permeability and prevent uptake during exposure.

The company has submitted a label and a Material Safety Data Sheet (MSDS) for the notified polymer which has adequate recommendations for disposal and handling accidental spillage.

9. EVALUATION OF TOXICOLOGICAL DATA

There is no requirement in the Act for toxicological data to be provided for chemicals assessed under the limited notification category, however the notifier has provided data for tests performed to meet the requirements of the interim Australian Standard 4020 “Products for use in Contact with Water Intended for Human Consumption with Regard to their Effect on the Quality of Water” (AS4020) (8).

9.1 Genotoxicity

9.1.1 *Salmonella typhimurium* Reverse Mutation Assay (9)

The genotoxic potential of substances that may be leached from MIEX™ resin were tested in two short term genotoxicity studies and these data are summarised below:

Strains:	TA 100, TA 98, TA 1535 and TA 1537
Concentration range:	10, 25, 50 or 100 μl leachate/plate in the presence and absence of an exogenous metabolic activation system (S9 mix)
Test method:	OECD Test Method (10)
Result:	negative, appropriate controls were used to validate the results

9.1.2 Micronucleus Assay in Chinese Hamster Lung Fibroblasts (11)

Cell line:	V79
Concentration range:	25, 50 and 100 μl of MIEX™ water and dimethyl sulphoxide (DMSO) leachate/plate in the presence and absence of an exogenous metabolic activation system (S9 mix)
Test method:	OECD Test Method (10)
Result:	negative; appropriate controls were used to validate the results

9.1.3 Cytotoxicity Assay in Chinese Hamster Lung Fibroblasts (12)

Cell line:	V79
Concentration range:	maximum volume of 100 μl of MIEX™ water and DMSO leachate/plate in the presence and absence of an exogenous metabolic activation system (S9 mix)

Test method:	OECD Test Method (10)
Result:	negative, no toxicity or precipitation observed at any dose tested

The intent of the interim Australian Standard 4020, "Products for use in Contact with Water Intended for Human Consumption with Regard to their Effect on the Quality of Water" (AS4020) (8) is to ensure that leachates of products which come into contact with drinking water are not cytotoxic to mammalian cells and are not genotoxic. The above mentioned test results demonstrate that the MIEX™ product containing the notified polymer in MIEX™ meets these criteria.

9.2 Overall Assessment of Toxicological Data

On the basis of toxicological data provided, due to the high molecular weight, water and fat insolubility, Polymer in MIEX™ is unlikely to be hazardous by ingestion, dermal contact or inhalation. Leachates of the MIEX™ resin do not demonstrate the potential to be genotoxic and are not cytotoxic. Based on the information provided by the notifier, Polymer in MIEX™ is not classified as hazardous according to Worksafe's Approved Criteria (5).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data are required for polymers of NAMW of greater than 1 000 according to the Act.

The chemical is a high molecular weight polymer containing quaternary ammonium groups on around 70% of the chains. Nabholz *et al*, state that aquatic toxicity in clean water increases exponentially with increasing cationic charge density for cationic polymers (including quaternary amines) with molecular weights of greater than 1 000 (13). The main concern is expressed for soluble cationic polymers.

The notified chemical is completely insoluble. It has a very high level of crosslinking, which produces a three dimensional structure with a very high molecular weight. Other cationic polymers used in water treatment tend to have a far lower level of crosslinking. As such, they "unravel" in water to produce linear polymers and possess a degree of solubility (14) .

Due to the polycationic nature of this polymer, acute toxicity studies in fish and algae were conducted, and are summarised as follows: (S = static; NC = nominal concentration).

Species	**Test (Conditions)**	**Result *(mg/L)***
Eastern Rainbow Fish (*Melanotaenia duboulayi)*	96 hour (S; NC)	LC_{50} > 1 000
Green Algae (*Selenastrum capricornutum*)	96 hour (S; NC)	E_rC_{50} = 900

Samples were prepared for the fish test by filtering a portion of the MIEX™ slurry through filter paper, with the resulting residue on the filter paper dried at 50°C for 4 hours. This dried sample was then weighed directly to treated tap water and stirred for approximately two minutes to make up the test solution.

The notifier has provided arguments supporting the methodology, claiming it represents a gross worst case exposure scenario. Product fines are still generally in the order of 5 to 10 microns in size, and are produced through the mechanical breakdown due to constant agitation during surface water treatment. It may be expected that the physical properties of these large molecules will be the same as the parent molecule. Therefore, for the purpose of this assessment, the fish test is acceptable.

During testing on algae, flasks were shaken twice daily. An EC_{50} of 156 ppm was determined for cell yield. One possible reason for this was that the shaking of the flask resuspended the MIEX™ beads causing a reduction in the light intensity available to algal cells.

No testing was conducted on cladoceran species, with the notifier citing recent work indicating that daphnids are approximately one order of magnitude more sensitive than fish to cationic polymers (15), and as noted above, testing on rainbow fish gave an LC_{50} of greater than 1 000 mg/L. It is noted that the use pattern for MIEX™ in this submission is related to potable water only, where exposure to the aquatic system is minimised. Therefore, for this assessment, the absence of data for Daphnia is acceptable, but should be required if higher exposure is likely.

Degradation Product

The notified polymer undergoes hydrolysis over time despite its lack of water solubility. This will cause the release of a quaternary ammonium into the water phase, as the hydrolysis product is soluble in water. This byproduct has the potential to be toxic, and quaternary ammonium compounds are generally thought to be surface active compounds that destroy exposed membranes such as the gill epithelium of fish (7). While no data appears to be available in the literature on the toxicity of this chemical to aquatic species, a structurally similar chemical, does have some toxicity data available. The mortality data from a test duration of 1 day indicate that the analogue is moderately toxic to fish species, with a measured LC_{50} of 10 mg/L for three fish species, Northern squawfish (*Ptychocheilus oregonensis*), Coho/silver salmon (*Oncorhynchus kisuth*); and Chinook salmon (*Oncorhynchus tshawytscha*) (7).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

MIEX™ will only be used as an ion exchange resin for the removal of DOC from surface waters prior to disinfection for use as drinking water. It will be used initially by the South Australian Water Corporation, and the Western Australian Water Corporation.

The following environmental hazard calculation has been conducted based on the use of this chemical in the Adelaide metropolitan area. There are 6 water filtration plants commissioned to serve metropolitan Adelaide (16). In calculating a predicted environmental concentration (PEC) the following assumptions have been used:

Annual water consumption[1]:	150 000 ML
Daily water consumption:	410 ML
Metropolitan sewer output per day:	150 ML

All water consumed will go through the filtration process prior to being distributed to consumers. The notifier indicates that a typical 50 ML plant will release 40 kg of MIEX™ with sludge which will be dewatered and disposed of to landfill, or sent to sewer. For these calculations, it will be assumed all sludge is disposed of to sewer. Using these assumptions, the PEC is calculated as follows:

A	Daily volume of water treated:		410 ML
B	Release of MIEX for 50 ML water treatment		40 kg
C	Release of MIEX for Adelaide water treatment	(A/50)*B	328 kg
D	Concentration of MIEX in STP		2.2 mg/L
E	Removal of MIEX from STP		80%
D	Final Concentration of MIEX in STP		0.44 mg/L

Release of sewer in the Adelaide area can occur in the mouth of the Port Adelaide river where large intertidal flats and mangrove swamps occur. Dilution can be negligible at certain times.

In determining the PEC, it was assumed that 80% of the MIEX™ present in the STP was removed with sludge. For such insoluble compounds, association with sludge would be expected to be higher than this. Additionally, the charged nature of the polymer indicates an even higher level of removal from the STP through increased binding to charged particles in sludge.

[1] Assumed as the same for Adelaide water consumption, 1992-93 [5]

The PEC is three orders of magnitude lower that the lowest median effect level observed during testing ($E_b C_{50}$ = 156 mg/L for algae) prior to release in receiving waters. Any notified chemical reaching receiving waters could be expected to settle and accumulate in sediments, where it will not be bioavailable.

Based on the tests provided with this submission, if the notified chemical is used in the typical manner outlined, the potential environmental hazard is low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer will be manufactured at one site in Australia as a component of the product MIEX™ and it will never be isolated. MIEX™ is an ion exchange resin that will be used to remove naturally occurring DOC from surface water prior to disinfection, for use as potable (drinking) water.

Due to its high molecular weight and physico-chemical properties the notified polymer is unlikely to be of toxicological significance. Based on the information summerised in Section 9, it is not classified as hazardous according to the Approved Criteria (5). Workers should however be aware that the monomer constituents of the polymer have the potential to cause a range of harmful effects if exposure occurs during manufacture. These effects include moderate toxicity following acute exposure by oral, dermal and inhalation routes, respiratory, skin and eye irritation (1, 2, 3). One component present at a high concentration is also a skin sensitiser, mutagenic and may cause adverse effects following chronic exposure (1). Published reviews of the other monomers report some effects of reproductivity and changes in blood parameters following chronic exposure via oral and inhalation routes respectively (1, 2). However, there is limited potential for occupational exposure to the notified polymer or individual components as the raw material ingredients will be weighed under exhaust ventilation and piped automatically to a closed reaction vessel where product manufacture occurs.

Workers may be dermally exposed to the notified polymer and/or product during transfer, when coupling and uncoupling of filling nozzles and packaging of the product . There is also the potential for exposure during cleaning and maintaining equipment but these operations will occur intermittently for limited periods of time.

The notified polymer is never isolated, and production of MIEX™ occurs in closed automated systems with minimal likelihood of exposure therefore, the occupational risk is considered to be low.

The enclosed manufacturing systems will also limit the likelihood of exposure to potentially hazardous monomers, and impurities in the formulated product.

Public exposure to the notified polymer is not expected to occur. The notified polymer will be removed from drinking water in the final stages of water treatment. Although the product MIEX™ contains a number of impurities, they will be present in drinking water at extremely low concentrations and are therefore unlikely to present significant risks to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to Polymer in MIEX^{TM} the following guidelines and precautions should be observed:

- Safe practices, which should be followed when handling any chemical formulation include:
    - minimising spills and splashes;
    - practising good personal hygiene; and
    - practising good housekeeping and maintenance including bunding of large spills which should be cleaned up promptly with absorbents and put into containers for disposal.
- It is expected that, in the industrial environment, protective clothing conforming to and used in accordance with Australian Standard (AS) 2919 (17) and protective footwear conforming to Australian/New Zealand Standard (AS/NZS) 2210 (18) should be worn as a matter of course. In addition it is advisable when handling the monomers and other product ingredients to wear chemical-type goggles, selected and fitted according to AS1336 (19) and meeting the requirements of AS/NZS 1337 (20); impermeable gloves (AS 2161) (21) should also be worn.
- the chemical should be approved for contact with drinking water in accordance with AS 4020 (8);
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the product, MIEX^{TM}, containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (22).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. There is the potential for a far wider use of the notified product, which could result in an increased exposure to the aquatic system. A secondary notification should be requested, including *Daphnia* testing, if the use pattern of the notified chemical changes to result in significant increased exposure of the aquatic system. No other specific conditions are prescribed.

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