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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in Jetsize AP – 1626

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Director
Chemicals Notification and Assessment

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1. APPLICANT

Eka (Australia) Pty Ltd has submitted a Polymer of Low Concern notification statement in support of their application for an assessment certificate for Polymer in Jetsize AP - 1626.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, import volume and details of the polymer composition have been exempted from publication in the Full Public Report.

Marketing Name:	Jetsize AP - 1626
Method of Detection and Determination:	Infrared (IR) spectroscopy, GPC.
Spectral Data:	An IR spectrum was provided.
Number-Average Molecular Weight (NAMW):	1 563
Maximum Percentage of Low Molecular Weight Species	
Molecular Weight < 500:	7.1%
Molecular Weight < 1 000:	13.9%
Polymer Stability:	Under normal conditions of use polymer is not expected to undergo any hydrolysis, thermal- or photo-degradation, not depolymerise, nor break down in any way.
Reactivity:	Not reactive. Equivalent weight of reactive functional groups > 5 000.
Particle Size:	Not applicable. Polymer is a component of an aqueous solution/dispersion when imported.

Charge Density:	Equivalent weight of charged groups is > 5 000.
Water Solubility:	Infinitely dilutable. The notifier states that the polymer does not form a true solution in water and does not form a suspension or dispersion as the particle size is 10 – 15 nm. In the remainder of report the term solution is used for convenience.

3. POLYMER COMPOSITION AND PURITY

Degree of Purity:	Residual monomers and other reactant levels were approximately 0.2% and the level of low molecular weight species (MW < 1 000) was 13.9%.
Maximum Content of Residual Monomers:	1% of species with molecular weight less than 380 as measured by GPC.
Hazardous Impurities:	Not detectable.
Non-hazardous Impurities (> 1% by weight):	None.
Additives/Adjuvants:	None.

4. PLC JUSTIFICATION

The PLC meets the criteria for a Synthetic Polymer of Low Concern as follows:

- The NAMW is greater than 1 000.
- The low molecular weight species are within the prescribed limits (less than 25% with MW < 1 000 and less than 10% with MW < 500 together with the fact that the combined FGEW for high concern reactive functional groups is greater than 5 000).
- The combined FGEW of cationic groups is greater than 5 000.
- The concentration of residual monomers or reactants does not render the polymer hazardous according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).
- The elemental criteria were satisfied.
- The polymer is stable.

5. PHYSICAL AND CHEMICAL PROPERTIES

The following properties refer to the aqueous dispersion to be imported containing 15% of the notified polymer.

Appearance at 20°C and 101.3 kPa:	Opalescent pale colour, liquid.
Boiling Point:	Approximately 100°C.
Specific Gravity:	1 020 kg/m^3
Water Solubility:	Infinitely dilutable (see notes below).
Hydrolysis as a Function of pH:	Not determined (see notes below).
Flammability Limits:	Not flammable.
Explosive Properties:	Not explosive.
Reactivity/Stability:	Not reactive.

Comments on Physico-Chemical Properties

The water solubility tests were carried out using a flask method based on OECD TG Method 105. The notified polymer was found to be dispersible with water at pH 7 and 10 at 5, 50 and 95% w/w concentrations at 20^{o}C. At pH 1 it was dispersible at 95% w/w concentration but at lower concentrations no specific figure could be determined as the polymer degraded under the acidic conditions.

No other physico-chemical test reports were provided by the notifier. The polymer is said to be stable, does not contains few reactive functional groups and is not expected to hydrolyse under normal environmental conditions, i.e. pH range 4-7.

6. USE, VOLUME AND FORMULATION

The notified polymer is to be used for surface sizing of paper during manufacture. It will be imported in 1 000 L Intermediate Bulk Containers (IBCs) as an aqueous solution at a concentration of 15%. Import volumes of the notified polymer are projected to be less than 100 tonnes per year for the first 5 years.

7. OCCUPATIONAL EXPOSURE

The IBCs containing the aqueous solution of the notified polymer will be transported to the notifier's warehouse and stored in a designated area. Exposure to two transport and storage workers should only occur in the event of accidental spillage for 1 hour per day on 6 days per year. At the notifier's site exposure of one worker during sampling for quality control testing may occur on 24 days per year for 3 hours per day.

Following transport of an IBC to a customer site, 3 production and filling personnel are

involved in connection of the IBC to a sizepress feed tank for 1 hour per day on 24 days per year. Connection of the IBC is to pipework which is part of a metering pump. Connection is accomplished by a screwed connector or a "kamlock" connector after which the top cap and discharge valve on the IBC are opened. Changeover of an empty IBC for a full one is estimated to take 10 minutes during which exposure of the hands to drips and spills is possible. The notifier states that exhaust ventilation is used and personal protective equipment (PPE) comprises overalls, safety goggles and PVC or rubber gloves.

Addition of the polymer solution to the paper machine occurs over 10 – 40 hours and is controlled automatically at a location away from the IBC and pump. Addition of the polymer solution to the feed tank occurs via a submerged pipe. The notified polymer is diluted to a concentration of 0.3% in the feed tank with hot (80°C) starch solution. The polymer is applied to the paper surface in the sizepress and any overflow is collected and returned to the feed tank. Spills are said to be infrequent and small in volume. Worker exposure may be possible during cleanup and workers will be wearing the PPE described above.

The wet paper web is dried over steam heated dryers. Local exhaust ventilation is used to control exposure to vapours.

Once the polymer is fixed to the paper, it is bound strongly, although exposure can occur when the paper is handled during routine sampling, re-processing and packaging. The notifier states that these operations are performed with minimal actual contact with the paper.

8. PUBLIC EXPOSURE

There is negligible potential for exposure of the public to the notified polymer. The notified polymer will be a component of processed paper and will not be available for use by the general public. Exposure of the general public to the notified polymer is likely to occur through contact with printed paper containing the dried bound polymer. The notified polymer is bound to printed paper rendering it effectively inert. The public could be exposed directly to the notified polymer in the event of a transport accident.

9. ENVIRONMENTAL EXPOSURE

9.1 Release

The notifier estimates that up to 0.05% of product will remain in empty import containers as residue. The containers will be rinsed on-site and the rinse water will be mixed into the next container of polymer dispersion. The containers will be recycled or reused following washing and the wash water will go to an on-site wastewater treatment plant.

The on-site bulk storage tank and transfer lines are enclosed within bunded areas. Release as a result of spills or line ruptures is unlikely but if it occurs the spill will either be recycled or washed into the on-site wastewater treatment plant where it may settle before disposal to landfill as sludge. The notifier has not estimated how much notified polymer may be lost as waste in this way or in transport accidents but it can be estimated from previous NICNAS assessments that 0.05% of the import volume of the polymer may be released to the

environment through spills.

The application system is a closed circulation system and the notifier has indicated that there will be no release during the normal application process. Any overflow from the application apparatus is returned to the sizepress feed tank for recycling.

9.2 Fate

The sources of polymer that may reach the aquatic environment include spills during transport from the docks, which will be very minor, and in the sludge from the on-site wastewater treatment plant. Thus, approximately 0.1% of the imported polymer will be disposed of to landfill. After degradation of the starch in which it is bound, it may be degraded or hydrolysed by enzymes or under acidic conditions (Budavari *et al.*, 1989), forming soluble products which may leach from landfill.

The fate of the majority of the polymer will be the same as that of the paper to which it is bound. The paper may be recycled, with the polymer likely to end up in the sludge formed during the process and disposed of to landfill. The majority of the paper is likely to be disposed of to landfill. The polymer bound to the paper will be insoluble and hydrophobic so will be inert and not available for leaching.

10. EVALUATION OF HEALTH EFFECTS DATA

Although no toxicological data were available for the notified polymer, the notifier provided two test reports on analogues. One of these studies addressed acute oral toxicity in rats (see below) and utilised an analagous polymer, Cyclopal KET which contains the same main monomers as the notified polymer but has differences in the minor components and has a much higher NAMW. Another analagous polymer, Cyclopal A, was used in a 90-day drinking water study in rats. This polymer contains the same monomers as the notified polymer in similar proportions except that it is missing a minor (2.1%) component. The latter study was in German but the notifier provided an english translation of the summary.

10.1 Acute Toxicity

10.1.1 Oral Toxicity (Sterner and Chibanguza, 1987)

Species/strain:	Wistar rats
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	oral (gavage)
Test method:	OECD TG 401
Mortality:	none

Clinical observations:	none
Morphological findings:	none
LD_{50}:	> 5 mL/kg (sample was a liquid administered undiluted)
Result:	An analogue of the notified polymer was of very low acute oral toxicity in rats.

10.2 Repeated Dose Toxicity (Neumann *et al.*, 1979) (one page summary)

An analogue of the notified polymer was added to the drinking water of Sprague-Dawley rats (50 animals (males and females) per dose group). The analogue was added at concentrations of 0, 0.2, 1.0 or 5.0% in tap water.

No changes were observed in behaviour, appearance, faeces, food and drinking water consumption, body weight, haematology, clinical chemistry, urine or organ weights. In macroscopic and microscopic examinations, minor pathological findings were observed at the top dose. These were not described and the summary notes they might have been spontaneous. The authors concluded that the lowest toxic dose was greater than 5%.

10.3 Overall Assessment of Toxicological Data

The acute oral toxicity of an analogue of the notified polymer was tested in Wistar rats. The LD_{50} was greater than 5 mL/kg. As the analogue may be expected to be highly water soluble like the notified polymer, it can be assumed that a concentrated solution was used (although this was not stated in the report) and that the analogue (and by default the notified polymer) is of low acute oral toxicity in rats. In a 90-day drinking water study in rats, an analogue of the notified polymer did not display systemic toxicity at a level of 5%.

The notifier expects the notified polymer to be slightly irritating to skin and eyes based on its alkaline nature. The pH of the imported polymer solution is listed on the MSDS for Jetsize AP-1626 as 7 – 9.

From analogue data it can be concluded that the notified polymer would not be classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) in terms of acute oral toxicity and repeated dose toxicity.

There are no hazardous impurities, additives or adjuvants to evaluate. The health hazards of the residual monomers are as follows:

Chemical	Health hazards	Regulatory controls
Residual monomers		
Exempt from publication	May cause sensitisation by inhalation; Toxic by inhalation; Irritating to eyes	TWA: 0.02 mg/m^3; STEL: 0.07 mg/m^3

	respiratory system and skin The levels of residual monomers in the notified polymer are well below the concentrations at which these risk phrases apply.

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

No ecotoxicological data are necessary for polymers of low concern with a NAMW > 1 000 according to the Act. However, the notifier supplied the following ecotoxicity data in support of the application. The test data are for an analogue polymer Cyclopal A and was generated according to OECD protocols.

Test	***Species***	***Results***
Acute Toxicity to Fish [OECD 203]	Zebra fish *Brachydanio rerio*	LC_{50} (96 h) > 1 000 mg/L See notes below.

The test was carried out using a static test system. The test tank was prepared by adding the test medium and the appropriate amount of the polymer from a stock solution. The tank was stirred for 2 h using a mechanical stirrer. Following preparation of the test media, 10 Zebra fish were added to each of the vessels. Ten control fish were also placed in a separate test vessel to which no test compound had been added. Temperature was maintained at 21.6 to 23.9°C, pH was between 7.7 and 7.8 and dissolved oxygen levels were between 8.2 and 8.9 mg/L.

No mortality or aberrant behaviour was observed in any of the fish at any of the observation times (0, 24, 48, 72 and 96 h) or in the control fish. From these observations, it can be concluded that the analogue polymer is not toxic to this species up to the limits of the test.

12. ENVIRONMENTAL HAZARD ASSESSMENT

Most of the polymer will be applied to paper by the roller process. Any released in the process waste will go to the on-site wastewater treatment plant. The notifier has indicated that all the effluent from the on-site treatment plant is recycled within the plant and that up to 0.1% of the polymer (i.e. 100 kg/annum) is removed from the site in the sludge. The polymer may leach from landfill in a very disperse manner once the starch is degraded.

The amount of notified polymer reaching the environment resulting from transport spills is anticipated to be minor. The fate of the majority of the polymer will be the same as that of the paper to which it is bound, the majority of which will be disposed of to landfill. Once the polymer has bound to the paper it will be in a stable matrix and will not leach.

The environmental hazard posed by this polymer if used in the proposed process is low.

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1 Hazard Assessment

The notified polymer meets the criteria for assessment as a synthetic polymer of low concern and it can be considered to be of low hazard. Supporting analogue data were consistent with this interpretation in that acute oral toxicity was very low and systemic toxicity was not observed in a 90-day drinking water study at levels up to 5%. On the basis of these data, the notified polymer is not classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) in terms of acute toxic effects and effects of repeated or prolonged exposure. The slight skin and eye irritation expected due to the potentially alkaline nature of the imported polymer solution would not lead to classification of the polymer as a hazardous substance.

13.2 Occupational Health and Safety

The notified polymer will be imported in 1 000 L IBCs from which small samples will be tested at the notifier's warehouse for quality. During sampling, limited exposure of laboratory personnel to the imported dispersion containing the notified polymer at 15% is further controlled by the use of safety goggles, PVC or rubber gloves and overalls. Exposure of transport or warehouse work is only likely in the event of accidental spillage.

The IBCs are connected to a sizepress machine for paper production by standard fittings or "kamlock" fittings. Flow into a feed tank does not occur until a valve is released. Therefore, transfer of the polymer in automated and exposure of workers is only possible when disconnecting an empty IBC. This exposure is limited to small drips and spills and is further controlled by the use of safety goggles, PVC or rubber gloves and overalls. Transfer of the polymer solution from the feed tank, in which the polymer is diluted to a concentration of 0.3%, to the sizepress machine is enclosed and occurs remote from the operator. Exposure is unlikely.

Once the notified polymer is fixed to the paper exposure can occur during handling while sampling re-processing or packing. However, at this stage the polymer is firmly bound to the paper and is unlikely to be bioavailable.

It can be concluded that there is a low risk of adverse health effects to workers involved in transport, storage, quality control testing, use or disposal of the notified polymer due to the low hazard, limited opportunity for exposure and the use of personal protective equipment.

13.3 Public Health

The public could come in contact with the notified polymer in the event of a transport accident or while handling coated paper. The risks to public health in each case are assessed as low.

14. MSDS AND LABEL ASSESSMENT

14.1 MSDS

The MSDS for the imported product containing the notified polymer was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data*

Sheets (NOHSC, 1994a).

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.

14.2 Label

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

15. RECOMMENDATIONS

To minimise occupational exposure to the notified polymer the following guidelines and precautions should be observed:

- Safety goggles, industrial clothing, footwear and impermeable gloves should be worn during occupational use of the products containing the notified polymer;
- Spillage of the notified polymer should be avoided. Spillage should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

Guidance in selection of goggles may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 2919 (Standards Australia, 1987); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/ Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/ Standards New Zealand, 1994).

16. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under subsection 64(1) of the Act, secondary notification will be required if the polymer characteristics cease to satisfy the criteria under which it has been accepted as a Synthetic Polymer of Low Concern. Secondary notification of the notified polymer shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

17. REFERENCES

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