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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Resin QRXP-1507

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FULL PUBLIC REPORT**Resin QRXP-1507****1. APPLICANT**

Rohm and Haas Australia Pty Ltd of 969 Burke Road Camberwell VIC 3124 (ACN 004 513 188) has submitted a notification statement in support of their application for an assessment certificate for the synthetic polymer of low concern (PLC) Resin QRXP-1507.

2. IDENTITY OF THE CHEMICAL

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

Marketing names: Resin QRXP-1507
Acryjet Black-357 Dispersion

3. POLYMER COMPOSITION AND PURITY

Details of the polymer composition have been exempted from publication in the Full Public Report.

4. PLC JUSTIFICATION

The notified polymer meets the PLC criteria.

5. PHYSICAL AND CHEMICAL PROPERTIES

Property	Result	Comments
Appearance	translucent colourless to yellowish liquid	aqueous dispersion
Melting point	not determined	the notified polymer is not isolated from aqueous dispersion
Density	1000 to 1200 kg/m ³	

Water solubility	> 1 mg/L	dispersible in water at > 5 g/100 mL
Particle size	not applicable	the notified polymer is not isolated from aqueous dispersion
Flammability	not flammable	
Explosive properties	not explosive	
Stability/reactivity	stable under normal environmental conditions	
Hydrolysis as function of pH		hydrolysis is not expected under environmental conditions (pH 4 - 9)
Partition coefficient		expected to be low due to anticipated relatively high water solubility
Adsorption/desorption		may be expected to adsorb to soils due to its polyanionic nature
Dissociation constant	pKa ~ 4.87	present as potassium salt, pH 7.5 – 8.5

6. USE, VOLUME AND FORMULATION

Use:

The notified polymer will be used as a pigment dispersant in ink jet printer cartridges for business and consumer use.

Manufacture/Import volume:

The notifier estimates that the import volume will be less than 5000 kg of notified polymer per annum during the first five years.

Formulation details:

The notified polymer will be imported in sealed inkjet printer cartridges and will not be reformulated or repackaged in Australia. Each cartridge will contain approximately 40 mL of ink, which contains < 5 % notified polymer.

7. OCCUPATIONAL EXPOSURE

Exposure route	Exposure details	Controls indicated by notifier
<i>End use (> 10000 workers, 0.25 hours per day, 50 days per year)</i>		
dermal	office workers will regularly change printer cartridges; very little contact with	none

wet ink containing the notified polymer is likely

<i>Transport and storage (20 workers, 2-3 hours per day, 2 days per year)</i>		
none	no exposure expected as the ink jet cartridges will be in sealed containers	none

<i>Retail (500 workers, no exposure frequency details provided)</i>		
none	no exposure expected as the ink jet cartridges will be in sealed containers	none

8. PUBLIC EXPOSURE

As a component of inkjet cartridges, the notified polymer will be available to the public. Exposure of the public to the notified polymer will occur through contact with printed paper containing the dried, bound polymer. Although dermal contact is the most likely route of exposure, very little of the notified polymer is expected to penetrate biological membranes due to its high molecular weight. Exposure of the public to the notified polymer may also occur in the event of an accidental spill. According to the MSDS provided, the spill area should be ventilated and contained with inert materials, such as sand and earth. Runoff from spills should be prevented from entering sewers and open bodies of water.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

There is little likelihood of release of the notified polymer at the storage sites as breakage of the ink cartridges is unlikely due to the robust packaging.

Environmental exposure will result from the disposal of empty cartridges and printed matter (estimated 95 %) as well as the possibility of accidental leakage of the cartridges during use. If it is assumed that 5 % of the ink remains in the spent cartridges then approximately 2 mL of ink or < 0.1 mL of the notified polymer will be disposed to landfill with each cartridge. As a worst case estimate, < 100 kg of the notified polymer will be disposed of to landfill in this manner in year 1 and < 250 kg per annum by year 5. Ink residues are expected to remain in the containers, although release could occur from deterioration of the discarded spent cartridge.

Some polymer may reach the environment during recycling in the wastewater generated through the de-inking process.

Release of the ink solution to the environment is not expected under normal use as ink cartridges are designed to prevent leakage. However, in the case of leakage, the ink will be wiped up and the absorbent material presumably disposed of in landfill.

9.2. Fate

The majority of the waste paper is expected to be disposed of directly to landfill via household and commercial garbage, with the notified polymer strongly bound to the paper. It is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified polymer. In the case of incineration of waste paper, the polymer would be destroyed, with the generation of water vapours and oxides of carbon and sulphur.

In addition to landfill and incineration, the paper recycling process will receive an undisclosed proportion of the ink printed on paper. During such processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, ink detachment from the fibres, pulp brightness and the whiteness of paper. The notifier states that de-inking wastes are expected to be neutralised and sent to a licensed waste disposal facility. Most of the polymer released to sewer will remain with the wastewater although some will stick to the sludge.

Polymer entering waterways either accidentally or through the recycling process, would be expected to dilute and disperse and eventually partition to the sediments due to its polyanionic nature. The polymer is not expected to cross biological membranes due to its high molecular weight. Therefore the notified substance is not expected to bioaccumulate.

10. EVALUATION OF HEALTH EFFECTS DATA

No residual monomers, hazardous impurities or additives and adjuvants are present at concentrations requiring classification of the product Acryjet Black-357 Dispersion as a hazardous substance. There are NOHSC exposure standards for carbon black (3 mg/m³ TWA) and t-butanol (100 ppm TWA, 150 ppm STEL) (NOHSC, 1995).

The notifier provided a number of analogue toxicity studies for the analogues Experimental Emulsion E-2852 and QR-1109. Experimental Emulsion E-2852 may be considered a good analogue, particularly for oral toxicity studies. QR-1109 is not as close structurally to the notified polymer as Experimental Emulsion E-2852; however it is expected that it would show more irritant effects than the notified polymer. These polymers were used in the form of aqueous dispersions, however the pH of the dispersions was not reported.

10.1 Acute Toxicity of Experimental Emulsion E-2852

The test substance consisted of an aqueous emulsion containing 37.6 % analogue polymer; doses were reported in terms of test substance rather than polymer. Studies were performed in accordance with Good Laboratory Practice principles.

Summary of the acute toxicity of Experimental Emulsion E-2852

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	rat	LD ₅₀ > 2000 mg/kg	Rohm and Haas, 1990a
acute dermal toxicity	rat	LD ₅₀ > 2000 mg/kg	Rohm and Haas, 1990b

10.1.1 Oral Toxicity (Rohm and Haas, 1990a)

<i>Species/strain:</i>	rat/Crl:CD BR
<i>Number/sex of animals:</i>	6/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	gavage; dose level 2000 mg/kg test substance; test substance used as received
<i>Test method:</i>	OECD TG 401
<i>Mortality:</i>	there were no premature decedents during the study
<i>Clinical observations:</i>	no clinical signs of toxicity were observed
<i>Morphological findings:</i>	no gross abnormalities were observed at necropsy
<i>LD₅₀:</i>	> 2000 mg/kg
<i>Result:</i>	the test substance was of very low acute oral toxicity in rats

10.1.2 Dermal Toxicity (Rohm and Haas, 1990b)

<i>Species/strain:</i>	rat/Crl:CD BR
<i>Number/sex of animals:</i>	6/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	occlusive patch; 24 hour exposure; dose level 2000 mg/kg test substance; test substance used as received
<i>Test method:</i>	OECD TG 402
<i>Mortality:</i>	there were no premature decedents during the study
<i>Clinical observations:</i>	red stained fur around the eyes and muzzle was observed for all animals on days 2 to 4 and persisted in some animals to the study end; no other clinical signs of toxicity were observed
<i>Morphological findings:</i>	no gross abnormalities were observed at necropsy
<i>Comment:</i>	test material adhered to the application site on day 1

LD₅₀: > 2000 mg/kg

Result: the test substance was of low dermal toxicity in rats

10.2 Acute Toxicity of QR-1109

The reports for this test substance consisted of a summary of results and a copy of the protocol. Full test reports were not provided. The test substance consisted of a clear light yellow liquid containing 49 % w/v analogue polymer in water; whether doses were corrected for concentration of analogue polymer was not reported. It is possible that the analogue polymer dispersion was pH adjusted to provide water solubility, but this was not mentioned in the reports. Studies were performed in accordance with Good Laboratory Practice principles.

Summary of the acute toxicity of QR-1109

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	rat	LD ₅₀ > 5000 mg/kg	Rohm and Haas, 1985a
acute dermal toxicity	rabbit	LD ₅₀ > 5000 mg/kg	Rohm and Haas, 1985b
skin irritation	rabbit	non-irritant	Rohm and Haas, 1985c
eye irritation	rabbit	non-irritant	Rohm and Haas, 1985d

10.2.1 Oral Toxicity (Rohm and Haas, 1985a)

Species/strain: rat/CRCO

Number/sex of animals: 10 male

Observation period: 14 days

Method of administration: gavage; dose level 5000 mg/kg test substance; test substance used as received

Test method: in house protocol 85P-77, similar to OECD TG 401

Mortality: there were no premature decedents during the study

Clinical observations: diarrhoea was observed for all animals on days 0 to 2; 6/10 also showed brown staining of the anogenital area; no other clinical signs of toxicity were observed

Morphological findings: no gross abnormalities were observed at necropsy

LD₅₀: > 5000 mg/kg

Result: the test substance was of very low acute oral toxicity in rats

10.2.2 Dermal Toxicity (Rohm and Haas, 1985b)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 6 male

Observation period: 14 days

Method of administration: occlusive patch; 24 hour exposure; dose level 5000 mg/kg test substance; test substance used as received

Test method: in house protocol 85P-89, similar to OECD TG 402

Mortality: one animal died between days 8 and 14

Dermal observations: very slight to well defined erythema resolved by day 7; negligible to very slight oedema resolved by day 2

Clinical observations: no clinical signs of toxicity were observed in 5/6 animals; the animal that later died showed passiveness, scant droppings, tan stained muzzle and distended abdomen

Morphological findings: liver abnormalities including 2 mm tan focus on the medial lobe and 0.5 - 1.0 cm white striations were observed in 3/6 animals; the animal which died during the study showed numerous abnormalities consistent with gastroenteritis and peritonitis

Comment: test material adhered to the application site

LD₅₀: > 5000 mg/kg

Result: the test substance was of low dermal toxicity in rats

10.2.3. Skin Irritation (Rohm and Haas, 1985c)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 6 male

Observation period: 7 days

Method of administration: occlusive patch; 4 hour exposure; dose level 0.2 mL test substance; test substance used as received

Test method: in house protocol 85P-60, similar to OECD TG 404

Dermal observations: all Draize scores for erythema and oedema were zero

Comment: test material adhered to the application site

Result: the test substance was non-irritating to the skin of rabbits

10.2.4. Eye Irritation (Rohm and Haas, 1985d)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 9 male

Observation period: 7 days

Method of administration: 0.1 mL test substance was applied to the corneal surface; test substance used as received; for 3 animals, the eye was irrigated with water 20 to 30 seconds after dosing

Test method: in house protocol 83P-362, similar to OECD TG 405

Comment: all Draize scores for conjunctival, iris and corneal effects were zero for irrigated and non-irrigated eyes; for one animal (non-irrigated) a linear striation of the cornea was observed after fluorescein examination at 48 hours and a 1 × 2 mm area of the cornea appeared hazy after fluorescein examination at 7 days

Result: the test substance was non-irritating to the eyes of rabbits

10.3. Overall Assessment of Toxicological Data

The analogue studies provided by the notifier are of limited applicability in determining the toxicity of the notified polymer, both because the analogue polymers lack many of the features of the notified polymer, and because of problems in the design and reporting of the studies.

For Experimental Emulsion E-2852, the doses of analogue polymer used for the dermal and oral acute toxicity studies were around 750 mg/kg. At this level, no clinical signs of toxicity due to the analogue polymer were observed. Observations of red stained fur around the eyes and muzzle were attributed by the study authors to the treatment procedure rather than the test substance itself.

For QR-1109, the doses were around 2500 mg/kg analogue polymer for the acute oral and dermal toxicity studies, 100 mg analogue polymer in the skin irritation study and 50 mg analogue polymer in the eye irritation study. No clinical signs of toxicity or skin or eye irritation were observed. The death of one animal in the acute dermal toxicity study was attributed to peritonitis and not considered to be due to treatment with the test substance.

Extrapolation of the irritation studies to the notified polymer is complicated by the pH of the test substance not being reported. However, the notified polymer dispersion is close to neutral pH, and any deviations to more acidic pH would be expected to increase the irritation potential of the test substance.

The notified polymer is not expected to be absorbed across biological membranes due to its high molecular weight. Based on the consistently negative results from the analogue polymers and the lack of functional groups expected to give biological activity in the notified polymer, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (NOHSC, 1999).

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

The notifier has supplied ecotoxicity studies on the analogue polymer, QR-1109, in aqueous dispersion as a clear yellow coloured liquid tested as received. The concentration of analogue polymer in the test substance was 49 %. For the fish and daphnia tests, the reports stated that the test substance was tested as 100 % active ingredient, while for the algae study, the report stated that no correction for concentration of analogue polymer was applied. The results are summarised in the following table.

<i>Test</i>	<i>Species</i>	<i>Results</i>	<i>Ref:</i>
96 h Static Acute Toxicity Test	Bluegill Sunfish (<i>Lepomis macrochirus</i>)	96 h LC ₅₀ > 1000 mg/L (nominal concentration)	Springborn Bionomics, 1985a
Acute Toxicity Test	Water Flea (<i>Daphnia magna</i>)	48 h LC ₅₀ > 1000 mg/L (nominal concentration)	Springborn Bionomics, 1985b
Growth Inhibition	Algae (<i>Selenastrum capricornutum</i>)	96 h EC ₅₀ = 250 mg/L (nominal concentration)	Hughes, 1985

Fish

The Acute Static Toxicity Test on bluegill sunfish (Springborn Bionomics, 1985a) was carried out over 96 hours. One replicate jar containing 10 fish was set up for each test concentration (nominally 130, 220, 360,600 and 1000 mg/L) and a test control. During the tests the photoperiod was 16 hours light and 8 hours dark, the temperature was 22°C ± 1°C, while the pH was 7.6 and conductivity 160 µmhos/cm.

No mortalities or behavioural or physical abnormalities were observed over the duration of the test for any test concentration. Therefore the 96 h LC₅₀ for QR-1109 was determined to be > 1000 mg/L.

Daphnia

The tests on daphnia (Springborn Bionomics, 1985b) were conducted over a 48 hour period. Three replicates containing five daphnids were prepared for each test concentration

(nominally 130, 220, 360, 600 and 1000 mg/L) and a test control. During the tests the photoperiod was 16 hours light and 8 hours dark, the temperature was 20 µmhos/cm, while the pH was between 7.1 and 7.9 and conductivity 500 µmhos/cm.

No mortalities or behavioural or physical abnormalities were observed over the duration of the test for any test concentration. Therefore the 48 h LC₅₀ for QR-1109 was determined to be >1000 mg/L.

Algae

A range finding test was conducted using six concentrations ranging from 0.01 to 1000 mg/L of the test substance QR-1109 to determine the appropriate concentrations for the definitive algal growth inhibition test (Hughes, 1985). Test concentrations of nominal concentrations of 100, 180, 320, 560 and 1000 mg/L were prepared by adding the required volumes of stock solution to the test medium. Three replicates of each concentration were formulated in 250 mL Erlenmyer flasks. Each of the replicates was inoculated with a 5-day old test culture, yielding a nominal initial concentration of 10000 cells/mL. Flasks were kept at 24°C ± 2°C and continuously shaken. Over the duration of the test three counts per replicate were made.

The mean standing crop values at 96 hours (SC96) in cell counts for each test concentration were expressed relative to the control, and percent inhibition was plotted against concentration to determine the EC₅₀. The percent inhibition, relative to control, based upon SC96 in cells/mL ranged from 0.8 % (at 100 mg/L) to 92.3 % (at 1000mg/L). The resulting EC₅₀ was determined to be 250 mg/L.

Conclusion

The test substance QR-1109 is practically non toxic to fish, daphnia and algae. The analogue is of limited validity but this assessment concludes that the notified polymer is also practically non toxic.

12. ENVIRONMENTAL RISK ASSESSMENT

There will be no reformulation or repackaging of the notified polymer in Australia, however all of the polymer will be ultimately released via disposal of empty ink cartridges or the printed paper to which the polymer is bound.

Incineration of the paper will result in destruction of the polymer, whereas recycling will result in most of the polymer being released in wastewater and the remainder to landfill in the sludge. The majority is anticipated to be disposed of to landfill via household and commercial garbage. The notified polymer is expected to associate with the soil matrix due to its polyanionic nature.

Extrapolations from ecotoxicity tests of an analogue polymer suggest that the polymer is practically non toxic to aquatic species and therefore the overall environmental hazard is predicted to be low.

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1. Hazard assessment

No toxicological information has been provided for the notified polymer and therefore the substance cannot be assessed against the Approved Criteria. Due to the high molecular weight of the polymer, and based on the consistently negative results from the analogue polymers and the lack of functional groups expected to give biological activity in the notified polymer, the toxicological hazard of the notified polymer is expected to be low. The polymer is not expected to be hazardous by dermal exposure as the high molecular weight will preclude absorption through the skin.

The Material Safety Data Sheet (MSDS) indicates that the product Acryjet Black-357 Dispersion is not classified as a hazardous substance but indicates that headaches, nausea and eye, skin and respiratory irritation may occur on exposure to this product. The t-butanol cosolvent is stated to potentially cause delayed liver and kidney damage on repeated exposure. The residual monomer concentrations in the finished polymer are below the cutoff levels for classification as a hazardous substance.

13.2. Occupational health and safety

There is little potential for significant occupational exposure to the notified polymer in the transport and storage or retail sale of the inkjet cartridges containing this polymer. There may be limited exposure for office workers changing inkjet cartridges, and to the dried ink on printed pages.

The main exposure route for the notified polymer will be dermal. Very small quantities of notified polymer are expected to be involved, as the ink content of a cartridge will be around 40 mL, at < 5 % notified polymer, and the user will normally have no contact with the very small amount of ink available at the cartridge print head. Dermal contact with the dried ink containing the notified polymer is not expected to pose any risk, as the quantities of notified polymer are very small, and the notified polymer is expected to be fixed to the paper and not be bioavailable.

The MSDS for the product Acryjet Black-357 Dispersion indicates that neoprene chemical resistant gloves should be worn whenever the material is handled. Due to the low exposure expected on handling the notified polymer in sealed inkjet cartridges, gloves would not be necessary for handling the cartridges.

Conclusion

The notified polymer is of low concern to human health and safety and no specific risk reduction measures are necessary.

13.3. Public health

The notified polymer is intended for use as a pigment dispersant in inkjet printer cartridges. Exposure of the public to the notified polymer will occur through contact with printed paper containing dried, bound polymer. However, since the notified polymer is unlikely to present a toxicological hazard, the potential for harm to the public through this exposure is considered low.

14. MSDS AND LABEL ASSESSMENT

14.1. MSDS

The MSDS of the product containing the notified polymer, Acryjet Black-357 Dispersion, provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994). It is published here as part of the assessment report. The accuracy of the information on the MSDS remains the responsibility of the applicant.

14.2. Label

Labels for the inkjet cartridges containing the notified polymer were not provided by the notifier, as no products have yet been produced. The notified polymer will not be imported in any form other than filled inkjet cartridges.

15. RECOMMENDATIONS

To minimise occupational exposure to Resin QRXP-1507, the following guidelines and precautions should be observed:

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b), workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

16. REQUIREMENTS FOR SECONDARY NOTIFICATION

Secondary notification may be required if:

- (i) any of the circumstances stipulated under subsection 64(2) of the Act arise. If any importer or manufacturer of the notified polymer becomes aware of any of these circumstances, they must notify the Director within 28 days; or
- (ii) the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

17. REFERENCES

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Springborn Bionomics, (1985b). Acute toxicity of QR-1109 PMN to Daphnids (*Daphnia magna*) Report No. BW-85-4-1761. Test Facility: Springborn Bionomics, Inc. Aquatic Toxicology Laboratory, Wareham MA, USA. (unpublished report)