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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Component of Rhodafac RS-610A-25

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Component of Rhodafac RS-610A-25

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Rhodia Australia Pty Ltd
352 Ferntree Gully Rd
NOTTING HILL NSW 3168

NOTIFICATION CATEGORY
Standard: Polymer (NAMW < 1000).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other name, names of analogues, CAS number, molecular and structural formulae, molecular weight, spectral data and purity.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: the physico-chemical properties were obtained using Rhodafac RS-610A-25 or a lyophilised sub sample; data on skin irritation, eye irritation, skin sensitisation and repeated dose toxicity were obtained using analogues.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Rhodafac RS-610A-25 contains the notified polymer.

MOLECULAR WEIGHT
< 1000

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	HPLC and IR spectroscopy.
Remarks	An IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
The notified polymer contains hazardous impurities totalling < 0.5%. Concentrations of hazardous impurities are below the relevant cutoffs for classification of the notified polymer as a hazardous substance.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED POLYMER (100%) OVER NEXT 5 YEARS
As an aqueous emulsion (> 10% notified polymer) in 200 L steel drums.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 100	< 100	< 100	< 100	< 100

USE
Paint component.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Unknown.

IDENTITY OF MANUFACTURER/RECIPIENTS
Exempt.

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 200 L steel drums, formulated into an aqueous emulsion, and transported in road tankers or 200 L drums to a paint manufacturing plant.

5.2. Operation Description

The notified polymer will be used in the manufacture of acrylic emulsion polymers which in turn will be used as a raw material in the manufacture of interior and exterior aqueous house paints. The notified polymer is pumped from the 200 L storage drums to a pressurised, 5 000 kg capacity reaction vessel vented to a caustic scrubber for vapour removal. Acrylic monomers and water are added to the reaction vessel to produce the polymer emulsion via an exothermic process. The polymer emulsion is then piped into a secondary holding vessel where water and more ingredients are added. After filtration to remove any coagulated solid material, the emulsion is piped into 20 000 L bulk storage tanks or 200 L steel sealed drums. Concentration of the notified polymer in the polymer emulsion is 1 - 2%.

Polymer emulsions containing the notified polymer are transported in 20000 L bulk containers or 200 L steel drums to customer sites for paint manufacture. At the customer site the polymer emulsion is stored at 1 to 49°C to prevent coagulation. The polymer emulsion will be pumped from 200 L drums or piped from 20 000 L bulk containers to open or closed 500 to 10000 L mixing vessels and blenders containing other ingredients. Concentration of the notified polymer in the paint is up to 0.3%. The paint from the mixing vessel is automatically filled into epoxy-lined 1, 4, 10 and 20 L steel cans under exhaust ventilation. These are stored and transported as required by road and rail to retail outlets.

The paint will most commonly be applied manually by brush and/or roller, with application by spray equipment less likely.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Emulsion plant operators	20 - 30	1 hour/day	90 days/year
QC workers	7	"	"
Transport workers	20	"	150 days/year
Paint making and QC sampling	60 - 75	6 hours/day	45 days/year
Paint technicians	30		
- laboratory manufacture		8 hours/day	45 days/year
- QC testing		1.5 hours/day	"
Paint packing	30	8 hours/day	"
Paint sales people and contractors	150	8 hours/day	150 days/year

Exposure Details

Exposure to the imported concentrated emulsion during acrylic polymer emulsion manufacture will be mainly dermal or ocular, arising from drips and spills during transfer from drums to reactor, and the notifier states that the workers involved will wear safety glasses and impervious gloves.

The possibility exists that during manufacture of the acrylic polymer emulsion, the enclosed reaction vessel may rupture in the event of a pressure build-up caused by fire or extreme heat and release toxic oxides of phosphorous, nitrogen and carbon. The dry form of the notified polymer can also burn and is considered a fire hazard.

During paint manufacture local exhaust ventilation will be in place over the mixing vessels to capture any volatile material at the source. Mixing vessels are located in the bunded areas.

Dermal and ocular routes would be the main avenues of exposure when connecting and disconnecting pipes, mixing and filling paint cans. The notifier states as a minimum, workers involved in paint manufacture should wear impervious (neoprene) gloves, coveralls and safety glasses.

The paint sales people may make dermal contact with the notified polymer at up to 0.3% in the paint when tinting with colourants. The notifier states the personal protective equipment worn by these workers would vary and that generally any skin contact with paint would be washed off immediately.

5.4. Release

RELEASE OF CHEMICAL AT EMULSION MANUFACTURING SITE

Environmental release is unlikely during importation, storage and transportation, and spillage during a transport accident is the most likely reason for environmental release. Individual container capacity (200 L), container specifications (steel drums) and emergency procedures would limit the extent of release. At the initial recipient's site, the imported polymer solution will be blended to form acrylic polymer emulsions for use to manufacture paint at numerous paint manufacturing facilities. Environmental controls at the emulsion manufacturing facility (eg. enclosed vessels, automated mixing and pumping) would limit the potential for accidental release to the environment. Equipment washings (reactor vessel, piping), containing an estimated 250 kg/annum (25 kg/batch and 5-10 batches/annum) of the notified polymer will be collected and treated at an on-site wastewater treatment plant (WWTP). Any spills would be likely to be contained and reused or disposed of in accordance with State/Territory waste disposal regulations.

Equipment wash waters generated after manufacture of the final emulsion product are expected to contain notified polymer (120 kg/annum, ie. 2 kg/batch and 60 batches per year). Approximately 120 kg of notified polymer (2% of drum contents) will remain as residues. Drum residues will be washed out and the washings sent to the onsite WWTP. At the WWTP the waste stream undergoes ultra-fine filtration, which may capture a proportion of the notified polymer for reuse. Use of water treatment products (ferrous sulphate, sodium hydroxide) will coagulate the notified polymer, and the resulting sludge will be transferred to settling pits on-site and allowed to dry before it is excavated and

sent to landfill for disposal in accordance with State/Territory waste disposal regulations. Effluent from the WWTP is neutralised and pumped to an on-site holding pond for evaporation, or used for on-site landscape irrigation. There is no direct release to sewer. Final emulsion product will be contained in 200 L drums or 20000 L bulk tanks on-site before road transport to paint manufacturing facilities in Australia. Total environmental release of the notified polymer from the emulsion manufacturing facility is estimated to be: 490 kg/annum (equipment washings to wastewater) and 120 kg/annum (drum residues to landfill).

RELEASE OF CHEMICAL FROM PAINT MANUFACTURING SITES

Emulsion will be pumped into 500 - 10000 L capacity bulk tanks at paint manufacturing facilities, located throughout Australia, and mechanically mixed and blended to form finished paint products. Engineering controls (eg. bunding) are likely to contain spills and leaks of products containing the notified polymer. Wash waters are likely to be reused in subsequent batches. Residues or spills, containing an estimated 2.5 kg/annum/facility of notified polymer, would be sent to licensed landfills. None of the paint manufacturing facilities are expected to dispose of wastewaters containing the notified polymer to municipal sewer.

RELEASE OF CHEMICAL FROM USE

Use of paints containing the notified polymer would be widespread and diffuse throughout Australia, with concentrations at urban areas/cities. Paint products will contain 0.1 - 0.3% (w/w) of the notified polymer. Most of the paint containing the notified polymer is applied to surfaces where it dries and hardens to a film with low potential for environmental release. However, in the long term painted surface may be repainted or painted materials may be demolished and sent to landfill for disposal or material recycling facilities. Brush/roller cleanup with water will result in copious amounts of wastewater containing low concentrations of the notified polymer (~500 kg of notified polymer/annum). The paint containing the notified polymer may also be sprayed onto surfaces, and overspray may occur onto drop sheets (eg. paper, cloth, plastic) or the immediate ground area. The former will be sent to landfill while the latter is likely to remain where it deposits.

5.5. Disposal

Wastes generated during industrial application of paint products containing the notifier polymer should be disposed of through a licensed waste contractor. Paint wastes generated during domestic use should be disposed of according to the instructions in Section 12. Brush/roller wastewater is typically disposed of to land (soil) and/or sewer; however, wastewaters generated from washing rollers/brushes should ideally not be sent to sewer for disposal, but should be contained, evaporated, with the residual dried paint waste sent to landfill for disposal; however, sewer disposal of this material is commonly practised and the notified polymer should not have an adverse effect on municipal STP operations or the environment under the exposure scenarios evaluated.

5.6. Public exposure

Manufactured paint will be sold through retail outlets. Concentration of the notified polymer in the paint will be up to approximately 0.3%. There is potential for exposure of the public to the notified polymer in paints used by do-it-yourself painters. The most likely routes of exposure to the notified polymer are skin and eye contact.

6. PHYSICAL AND CHEMICAL PROPERTIES

The data for the physico-chemical properties were obtained via tests on a pure sample of Rhodafac RS-610A-25 and a lyophilised sub sample of this chemical, known as B.

Appearance at 20ºC and 101.3 kPa clear colourless liquid

Boiling Point >146 $\pm$ 5°C at 102 $\pm$ 1 kPa

Remarks The test was carried out using B which is the residue left after lyophilisation of the notified polymer and is expected to be similar to a pure sample of the notified polymer.

TEST FACILITY CanTest (1998)

Pour Point 20 ± 1°C

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks The test was carried out using B.
TEST FACILITY CanTest (1998)

Density 1150 kg/m^3

METHOD OECD TG 109 Density of Liquids and Solids.
Remarks A modified pycnometer method was used to determine density of B. This modified method was required due to the high viscosity of B
TEST FACILITY CanTest (1998)

Vapour Pressure < 1.3 x 10^{-2} kPa at 25°C

METHOD OECD TG 104 Vapour Pressure.
Remarks The isoteniscope method was employed for vapour pressure determination. The detection limit was 13 Pa and the observed vapour pressure of B at 25°C was less than 13 Pa.
TEST FACILITY CanTest (1998)

Water Solubility > 0.54 g/L at 23°C

METHOD OECD TG 105 Water Solubility
Remarks Screening Method: Flask Method. Pure water and different amounts of B were homogenised at 23 ± 1°C, with determination made by observation of cloudiness. The solubility of B was > 0.54 g/mL at 23 °C. At 0.97 g/mL, the water was absorbed by B and a homogenous gel was obtained.
TEST FACILITY CanTest (1998)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
Remarks HPLC analysis.

pH	*T (°C)*	*$t_{½}$*
4	50	not reported
7	50	not reported
9	50	not reported

Remarks Hydrolytically stable in buffers at pH 4, 7 and 9 at 50 °C. The calculated extents of hydrolysis were negative due to the slightly lower concentrations observed by HPLC in the reference solutions than in the hydrolysis solutions, potentially due to the surfactant properties of the test substance.
TEST FACILITY CanTest (1998)

Partition Coefficient (n-octanol/water) log Pow = ≤ -1 ± 1 at 23°C

METHOD Molecular modelling computer algorithms based on OECD TG 107 Partition Coefficient (n-octanol/water).
Remarks Flask Method. Rhodafac (804.72 mg) was diluted in pure water (50 mL) for preparation of aqueous stock. This was added to saturated octanol after mixing the contents in each phase determined by Flow Injection UV Analysis.
TEST FACILITY CanTest (1998)

Adsorption/Desorption
– main test

METHOD OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.

Soil Type	*Organic Carbon Content (%)*	*pH*	*Koc (mL/g)*
Sand	1.9	5.1	Not interpretable
Loam (1)	0.4	5.09	"
Loam (2)	7.8	9.0	"

Remarks Standard tests were run at a concentration of 1.02 mg/mL for 16 hours but the HPLC-UV method was not sufficiently sensitive. Therefore, based on molecular modelling calculations and qualitative HPLC test results, it was estimated that > 50% of the notified polymer would adsorb to soils and < 40% would desorb. Detection of the chemical in adsorption solutions of the sand and loam (1) soils indicate a Koc of 1; however, it was not detected in solutions from soil 3 indicating that more than 50% of the chemical adsorbed to this soil. These results should be treated with caution.

TEST FACILITY CanTest (1998)

Dissociation Constant $pK_{a1} = 1.6$; $pK_{a2} = 6.8$ (estimated).

Remarks These results indicate that in the environment part of the chemical would exist in the anionic form.

Flash Point > 93°C

Flammability Limits Not flammable.

Autoignition Temperature Does not autoignite.

Explosive Properties Not explosive.

Reactivity Stable under the condition of use.

7. TOXICOLOGICAL INVESTIGATIONS

The notified polymer was tested for acute oral toxicity, bacterial mutagenicity and clastogenicity in mouse bone marrow erythrocytes as a 25% aqueous emulsion.

Irritancy, repeated dose toxicity and skin sensitisation were tested with analogues (E, F, G, H and I) whose identity is included in the Assessment Report but not in this Full Public Report.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50: 100 < LD50 < 2000 mg/kg bw	not toxic via the oral route
Rabbit, skin irritation	corrosive
Rabbit, eye irritation	severely irritating
Human, repeat insult patch test	no evidence of sensitisation.
Rat, feeding study - 90 days.	NOEL = 530 mg/kg/day bw
Dog, feeding study – 15 weeks.	NOEL = 300 mg/kg/day bw
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vivo mouse bone marrow micronucleus test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE 25% aqueous emulsion of notified polymer.

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain Rat/CD® [Crl:CD®(SD)BR]
Vehicle None.
Remarks - Method 1.96 mL/kg of test substance administered orally by gavage.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5/sex	2000	None.

LD50 > 2000 mg/kg bw
Signs of Toxicity None.
Effects in Organs None.
Remarks - Results

CONCLUSION The test substance containing < 100% notified polymer is of low toxicity via the oral route.

TEST FACILITY Nucro Technics (1998a).

7.2. Acute toxicity - dermal

No data were submitted for acute dermal toxicity. The notifier states on the basis of very low acute oral toxicity, and the expected low dermal absorption based on relatively high molecular weight (> 500) and low water-octanol partition coefficient (log P_{ow} = -1), it is unlikely to be toxic via the dermal route.

7.3. Acute toxicity - inhalation

No data were submitted for inhalation toxicity. The notifier states on the basis of very low acute oral toxicity and the expected low vapour pressure it is unlikely to be toxic via the inhalation route.

7.4. Corrosion/Irritation – skin

7.4.1 Irritation

TEST SUBSTANCE Analogue E.

METHOD Draize (1959).
Species/Strain Rabbit/New Zealand White
Number of Animals 6/sex not identified
Vehicle None.
Observation Period 72 hours.
Type of Dressing Semi-occlusive.
Remarks - Method Substance was held under the dressing for 24 hours.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	4	4	72 hours	4
Oedema	3.2	4	"	3

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results Blanching of the skin was observed in all rabbits at 24 hours and in 2 rabbits at 72 hours for intact skin.

CONCLUSION Analogue E is severely irritating to skin.

TEST FACILITY Consumer Product Testing (1980a).

7.4. Irritation – skin
7.4.2 Corrosion

TEST SUBSTANCE Analogue E.

METHOD Draize (1959).
Species/Strain Rabbit/New Zealand White
Number of Animals 6/sex not identified
Vehicle None.
Observation Period 7 days.
Type of Dressing Semi-occlusive.
Remarks - Method Substance was held under the dressing for 4 hours.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	4	4	7 days	4
Oedema	3.8	4	"	4

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results Blanching was observed in all rabbits at 4, 24 and 48 hours and crust was observed in 3 rabbits at 48 hours and all rabbits at 7 days.

CONCLUSION Analogue E is corrosive to skin.

TEST FACILITY Consumer Product Testing (1983).

7.5. Irritation - eye

TEST SUBSTANCE Analogue E.

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 6/sex not identified.
Observation Period 7 days.
Remarks - Method

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	2.4	3	7 days	3
Conjunctiva: chemosis	3.1	4	"	3
Conjunctiva: discharge	1.8	2	"	2
Corneal opacity	3.3	4	"	4
Iridial inflammation	1	1	"	1

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results: Two animals exhibited fibrovascular connective tissue in relation to corneal effects, 2 animals exhibited bloody discharge in relation to conjunctival effects; blanching was observed in 2 animals at 1 day, 4 animals at 3 days and 5 animals at 4 days post instillation.

CONCLUSION: Analogue E is corrosive to the eye.

TEST FACILITY: Consumer Product Testing (1980b).

7.6. Skin sensitisation – human volunteers

TEST SUBSTANCE: Analogue F.

METHOD: The Shelanski and Shelanski test (described in Patrick E and Maibach H I, 1995)) is comparable to the original Draize human repeat insult patch test but employs 15 consecutive induction patches to the same site and if erythema and/or oedema develops during induction the following patch should be moved to an adjacent untreated area. 2-3 weeks after the last induction a challenge patch is applied for 48 h and scored. The induction patch responses are also noted and interpreted as evidence of cumulative irritation.

Study Design: Shelanski and Shelanski.
Study Group: Fifty human volunteers.
Vehicle: Water.
Induction Procedure: General procedure described above.
Rest Period: Usually 3 applications are applied per week.
Challenge Procedure: Typically a challenge patch is applied to a naïve site.
Remarks -Method: A summary report only was provided. The test predates GLP guidelines.

RESULTS

Remarks - Results: No skin reactions were seen during induction or challenge.

CONCLUSION: A human repeat insult patch test was conducted using analogue F diluted with water to 50%. The notified chemical was non-irritating and non-sensitising under the conditions of the test.

TEST FACILITY: Industrial Biology Research Laboratories (1959).

7.7. Repeat dose toxicity

7.7.1 Feeding study in rats

TEST SUBSTANCE: Analogue F or a mixture of analogues G, H and I.

METHOD: Internal protocol.
Species/Strain: rat/FDRL strain
Route of Administration: Oral – diet.
Exposure Information: Total exposure days: 90 days.

Remarks - Method The test predates GLP guidelines and formal test guidelines. The test protocol included similar observations to OECD TG408. An abbreviated report only was provided.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	22/sex	0 (Mixture of analogues G, H and I)	Nil
II (low dose)		254 (Mixture of analogues G, H and I)	"
III (mid dose)		530 (Mixture of analogues G, H and I)	"
IV (high dose)		1080 (Mixture of analogues G, H and I)	"
V (high dose)		1080 (Analogue F)	"

Clinical Observations
High (analogue F) dose male and female rats showed growth retardation compared to the controls.

Laboratory Findings – Clinical Chemistry, Haematology.
No effects observed that were described as treatment related.

Effects in Organs
Dose related hepatomegaly (enlarged liver) was observed in all male animals fed with the mixture. High and mid dose males fed with the mixture exhibited increased relative and absolute kidney weight. High dose rats receiving F showed a relative increase in kidney weight. Mid (mixture) and high (F) dose males exhibited a significant mean absolute weight decrease in adrenals, however on a ratio to body weight basis only mid dose males exhibited a significant decrease in adrenal weight compared to the controls. High (mixture) dose females exhibited increased absolute liver weights compared to controls. High and mid (mixture) dose females exhibited an increase in absolute adrenal weight but the ratio of adrenal to body weight was not found to be statistically significant. Mid (mixture) dose females recorded a significant decrease in relative ovarian weights.

Dilation of the pelvis of the kidney (hydropelvis) was observed in all treated groups (not in all animals) but not in controls. The study states hydropelvis is a common occurrence in Wistar-derived strains and has been observed in many other studies carried out in this laboratory and hence it is unlikely to be treatment related with any of the mixture analogues.

Remarks – Results
There were no deaths in any group. Food and water consumption was similar in the control and treated groups. However the growth rate was significantly depressed in the high dose F animals. No adverse effects in hematopoietic function or clinical parameters were observed. Absolute and relative increases in organ weights had no supportive histopathological changes. The NOEL was 530 mg/kg/day based on depressed growth rate at the high dose.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 530 mg/kg bw/day in this study, based on depressed growth rate at the high dose.

TEST FACILITY Food and Drug Research Laboratories (1967a).

7.7.2 Feeding study in dogs

TEST SUBSTANCE Analogue F or a mixture of analogues G, H and I.

METHOD Internal protocol.
Species/Strain Dog/Beagle.
Route of Administration Oral – diet.
Exposure Information Total exposure days: 15 weeks.
Remarks - method The test predates GLP guidelines and formal test guidelines. The test protocol included similar observations to OECD TG408. An abbreviated report only was provided.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	4/sex	0 (Mixture of analogues G, H and I)	Nil
II (low dose)	3/sex	150 (Mixture of analogues G, H and I)	"
III (mid dose)	3/sex	300 (Mixture of analogues G, H and I)	"
IV (high dose)	3/sex	600 (Mixture of analogues G, H and I)	"
V (high dose)	4/sex	600 (Analogue F)	"

Clinical Observations

High dose (F) male and females showed growth retardation compared to the controls. Other dogs, including controls, lost weight intermittently as food intake varied.

Laboratory Findings – Clinical Chemistry, Haematology.

No effects observed that were described as treatment related.

Effects in Organs

The liver to body weight ratio was significantly increased in high dose males (F) and high dose females (F and mixture), relating to the lower body weight in treated animals compared to controls. Females receiving F exhibited an absolute kidney weight loss compared to the controls. However, a relative increase in kidney weight was observed in low and mid dose females (mixture) and in high dose males (mixture and F). This was attributed to the weight loss in high dose animals. Mid dose females (mixture) exhibited an absolute increase in ovarian weight and a relative increase at all three doses. Low dose (mixture) and high dose (F) dogs exhibited a relative increase in adrenal weight compared to the control group. High dose (F) males and females exhibited a relative increase in thyroid weight and an absolute decrease in brain weight, respectively.

Chronic inflammatory cell accumulation in the submucosa of the gallbladder was observed in dogs given the mixture at all doses and F at high dose. The authors concluded this was not treatment related. Adrenal cortical hyperplasia was observed in 2 mid (mixture) and 4 high dose (mixture) animals and 4 high dose (F) animals.

Remarks – Results

There were no deaths in any group. Food and water consumption of all dose groups increased in a similar fashion to control group. No adverse effects in hematopoietic function or clinical parameters were observed. Absolute and relative increases in liver and kidney weights had no histopathological findings. High dose dogs that exhibited a relative increase in adrenal weight had associated cortical hyperplasia.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 300 mg/kg bw/day in this study on the basis of growth retardation; organ weight changes at the mid and lower doses were of questionable biological significance and well within the usual ranges of animal variability.

TEST FACILITY Food and Drug Research Laboratories (1967b).

7.8. Genotoxicity - bacteria

TEST SUBSTANCE Rhodafac RS-610A-25.

METHOD OECD TG 471 Bacterial Reverse Mutation Test Plate incorporation procedure.

Species/Strain	*S. typhimurium*: TA98, TA1538, TA1535, TA1537 and TA100
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 10 - 1000 µg/plate. b) Without metabolic activation: 10 - 1000 µg/plate.
Vehicle	Water.
Remarks - Method	Two independent tests were performed in triplicate.
Remarks - Results	The test chemical was cytotoxic at 5.0 mg/plate in the preliminary test; positive controls demonstrated the sensitivity of the test and negative controls were within acceptable limits. There was no significant increase

in the number of revertants with the test article compared to the negative control for all tester strains; there was no evidence of a dose-dependent response, and the mean reversion frequency following treatment with the test article was less than two times that of the corresponding controls for all tester strains at all concentrations.

CONCLUSION The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Nucro Technics (1998b).

7.9. Genotoxicity – in vivo

TEST SUBSTANCE Rhodafac RS-610A-25.

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain mouse/Crl:CD-1®(ICR)BR
Route of Administration Oral – gavage.
Vehicle Water.
Remarks - Method 6 mice received 0, 500, 1 000 or 2 000 mg/kg notified polymer in distilled water by gavage; bone marrow was sampled 24 and 48 hours after dosing

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
1	6 males	0	24, 48
2	"	500	24, 48
3	"	1000	24, 48
4	"	2000	24, 48

RESULTS
Remarks - Results The notified polymer did not induce an increase in the frequency of micronucleated polychromatic erythrocytes; cyclophosphamide, the positive control, demonstrated the sensitivity of the test; there was no statistically significant decrease in the PCE:NCE ratio, demonstrating that the test article was not cytotoxic to the bone marrow.

CONCLUSION The notified polymer was not clastogenic under the conditions of this test.

TEST FACILITY Covance Laboratories (1998).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer.
METHOD	OECD TG 301 D Ready Biodegradability: Closed Bottle Test.
Inoculum	Not stated
Exposure Period	30 days
Auxiliary Solvent	None
Analytical Monitoring	Not stated
Remarks - Method	Full test report not provided.
RESULTS	
Remarks - Results	Only 2% of the theoretical oxygen demand was observed.
CONCLUSION	Not readily biodegradable
TEST FACILITY	Rhodia Inc Cranbury Analytical & Microbiological Services (1998).

8.1.2. Bioaccumulation

Based on the low partition co-efficient (Log Pow ≤ 1 ± 1 at 23 °C) and the high water solubility, the notified polymer is not expected to exhibit significant bioaccumulation.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue GAFAC LO-529
METHOD	Acute Fish Toxicity Test - Flow-through test according to the Committee on Methods for Toxicity Tests with Aquatic Organisms (1975). In-house procedure Biospherics Inc AQ-102.
Species	Rainbow trout (*Oncorhynchus mykiss*) Length 44.6 (38.8-51.0) mm, Weight 0.71 (0.43-1.10) g, Age 5 months.
Exposure Period	96 hours
Auxiliary Solvent	None.
Water Hardness	112 mg $CaCO_3$/L
Analytical Monitoring	None.
Remarks – Method	Temperature 12.2 (12-12.5) °C, pH 6.7-7.7, Photoperiod 16 light: 8 dark. Dissolved oxygen 6.8-10.4 mg/L. Within acceptable limits.

RESULTS

Concentration mg/L		*Number of Fish*	*Cumulative Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
0	-	10	0	0	0	0
1.0	-	10	0	0	0	0
1.8	-	10	0	0	0	0
3.0	-	10	0	0	0	0
5.0	-	10	1	1	2	2
8.0	-	10	5	9	10	10

LC50	5800 µg/L at 96 hours (nominal).
NOEC (or LOEC)	1800 µg/L at 96 hours (nominal).
Remarks – Results	96 h LC50 values for fish for various alkyl ether sulphates (AES) analogues occur in the range of 390-450000 µg/L (Marsden et al., 2001).

	The analogue has some structural differences to the notified polymer but is an acceptable surrogate. AES may be used as surrogates as they are the closest common analogue.
CONCLUSION	The substance tested is toxic to fish (LC50 1-10 mg/L).
TEST FACILITY	Biospherics Inc. (1983)

8.2.2. Acute/chronic toxicity to aquatic invertebrates

No data were available for the notified polymer. Literature sources indicate a 96 h L(E)C50 value for an AES analogue of 1170 μg/L, and 21 d chronic L(E)C50 values in the range of 370-740 μg/L when *Daphnia* were exposed to $C_{13.67}$ $AE_{2.25}$ (Madsen et al., 2001). These data suggest that aquatic invertebrates may potentially be more sensitive to the notified polymer than fish.

8.2.3. Algal growth inhibition test

No data were available for the notified polymer. 48-72 h EC50 values for toxicity of AES for algae species occur in the range 32000-65000 μg/L. Chronic (21 d) tests with algae show >90% growth inhibition when exposed to concentrations of 20000-30000 μg/L (Madsen et al., 2001). AES show slight toxicity to algae.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

In landfill, the notified polymer is contained within a polymer matrix, and is unlikely to migrate or leach to the wider environment. Due to alternative disposal/recycling methods, sewer discharges from emulsion and paint manufacturing facilities are not expected to contain the notified polymer. Wastewaters generated from cleaning brushes/rollers used to apply the paints may potentially contribute up to 500 kg of the notified polymer each year to sewer. In a national wastewater system, this may result in an average wastewater concentration up to 0.34 μg/L assuming no sewage system attenuation. This assumes the Australian population of 20 million people discharges 200 L of wastewater per person per day into the sewerage system. Predicted environmental concentrations (PEC) for the notified polymer for inland river discharges are 0.34 μg/L, assuming no attenuation or dilution, and 0.034 μg/L for ocean discharges, assuming a 10-fold dilution factor.

9.1.2. Environment – effects assessment

The limited aquatic toxicity data available for an analogue for freshwater fish indicate a 96 h LC50 for fish of 5800 μg/L. A predicted no effect concentration (PNEC) for aquatic organisms of 5.8 μg/L has been derived using an assessment factor approach by dividing the lowest LC50 value by a safety 1000. A PNEC of very similar magnitude would be derived using AES analogue data.

9.1.3. Environment – risk characterisation

The risk quotient values (PEC/PNEC) estimated based on the scenario of discharging up to 500 kg of the notified polymer to sewer each year (assuming no sewerage system attenuation/biodegradation) in Australia are 0.006 (0.034/5.8; marine) and 0.06 (0.34/5.8; inland rivers). Therefore, the proposed use of the notified polymer is unlikely to pose an unacceptable risk to the aquatic life. Likely attenuation and biodegradation in the sewerage system, sewerage treatment works, and in the aquatic compartment, as well as reclamation of effluent and biosolids, further reduces the aquatic risk. To exceed the benchmark concentration, respectively, an estimated 16-fold increase in sewer discharge above that estimated would be required. The notified polymer in landfilled wastes is likely to remain within the polymer matrix and landfill environment but will eventually degrade over time to simple compounds of the elements present.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified polymer as a concentrated aqueous emulsion will be transferred from 200 L drums to a reactor vessel to produce acrylic emulsion polymers. Exposure will be to drips and spills during transfer and clean up, should be mainly dermal and intermittent and will be controlled by the use of personal protective equipment.

The concentration of notified polymer in the emulsion polymer is low, 1 – 2%. Consequently, exposure of workers will be low during transport storage and formulation into paints. Workers involved in paint manufacture typically wear protective clothing, boots, goggles and gloves. Therefore, exposure to the notified polymer, already low, will be further reduced. In addition, local exhaust ventilation will be used to control the inhalation exposure to fumes and aerosols.

Mixing and tinting of paint at retail outlets can lead to intermittent exposure, however, the notified polymer is in the paint at 0.3% and exposure will be low.

9.2.2. Public health – exposure assessment

The low level of notified polymer in the finished paint, 0.3%, means that skin and eye exposure will be low even in the event of paint remaining on the skin for extended periods of time (up to several hours).

9.2.3. Human health - effects assessment

No inhalation or acute dermal toxicity studies have been performed on the notified polymer. The notifier made a claim for variation of schedule data requirements for an acute inhalation toxicity study, on the basis of anticipated low exposure, as the notified polymer is in the form of a slightly volatile liquid (vapour pressure 1.3 x 10^{-3} kPa at 25°C). The notifier also made a claim for variation of schedule data requirements for an acute dermal toxicity study, on the basis of anticipated low exposure, the notified polymer has a likely low acute oral toxicity, high molecular weight (> 500) and low water-octanol partition coefficient (log P_{ow} = 1). Both claims for variation were accepted on the basis of anticipated low exposure.

The notified polymer was tested for acute oral toxicity in rats up to a limit dose of 500 mg/kg bw (equal to 2000 mg/kg bw of the formulation tested). No adverse effects were seen. Analogue data were presented for skin and eye irritation and corrosion. The analogue used is related to the free acid of which the polymer is a salt. The results for the free acid indicated that the analogue was corrosive to skin and eyes of rabbits. This is consistent with the low pH of the test substance. The analogue does not accurately represent the notified polymer in that it has a very different pH and therefore different irritant effects. The severity of the pH dependent irritant effects may mask more subtle effects, and, in the absence of results to the contrary, the notified polymer should be considered an irritant. Limited analogue data from patch testing from humans suggest the notified polymer is not likely to be a skin sensitiser in humans.

A 13-week repeated dose oral study in rats using analogues showed no adverse effects in haematopoietic function or clinical parameters. Growth rate was depressed in high dose animals, however absolute and relative increases in organ weight had no supportive histopathological abnormalities. The NOEL is 530 mg/kg/day. A 15-week repeat dose oral study in dogs using analogues showed no adverse effects in haematopoietic function or clinical parameters. Absolute and relative increases in liver and kidney weights had no supportive histopathological abnormalities. High dose animals that exhibited a relative increase in adrenal weight showed adrenal cortical hyperplasia. The NOEL is 300 mg/kg/day based on this finding. The analogues used for these studies were considered to be sufficiently close to the notified polymer that the results can be taken as representative.

The notified polymer was non-mutagenic in a bacterial mutation assay. It did not induce a significance increase in the frequency of micronucleated mouse bone marrow polychromatic erythrocytes in an *in vivo* study.

Based on analogue data the notified polymer is determined to be a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National

Occupational Health and Safety Commission, 1999). The corrosive effects observed for the analogue are thought to be due to its low pH and were not reflected in the human patch test report using a different analogue; however in the absence of results to the contrary, the notified polymer should be considered to be irritating to the eyes and skin.

9.2.4. Occupational health and safety – risk characterisation

Reformulation

During manufacture of polymer emulsion, workers involved in operating the reactor have the highest chance of dermal and eye exposure to the notified polymer in the manufactured form. Workers involved in other processes, such as quality control testing and equipment maintenance, may also experience dermal and eye exposure to the notified polymer however the duration and frequency of exposure would be less, and after reformulation, the chemical is present at lower concentrations (up to 2% and no longer a hazardous substance). All workers involved in reformulation activities, including quality control and equipment maintenance will need to wear impervious gloves and safety glasses and overalls. Polymer emulsion is manufactured in a closed and ventilated vessel.

Paint manufacture

The main group of paint manufacture workers likely to be exposed to the notified polymer on a regular basis are those involved in loading and operating the blender, quality control personnel and personnel involved in paint filling operations. The notified polymer in the polymer emulsion is less than 2% and in the paint is approximately 0.3%. However, the chemical is a severe skin and eye irritant and adequate controls should be in place to prevent dermal or ocular exposure. Paint manufacture is carried out in closed or open mixing vessels with local exhaust ventilation. The notifier states workers involved in paint manufacture, as a minimum should be attired with impervious (neoprene) gloves, coveralls and safety glasses.

Paint application

End use of the paint in domestic and commercial situations may potentially result in frequent exposure. Overalls may typically be worn by end uses, however it is unlikely that gloves or goggles would routinely be used. The risk of adverse health effects from the notified polymer is low given that is present below 0.3% and is not a hazardous substance.

9.2.5. Public health – risk characterisation

There is potential for public exposure of the notified chemical arising from its use in paints, but the low concentration in the final paint products indicates a negligible risk to public health.

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

10.1. Hazard classification

Based on the available data the notified polymer is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R38: Irritating to skin;
R41: Risk of serious damage to eyes

and

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

Skin irritant (category 2) and eye irritant (category 1)

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, the notified polymer is not considered to pose an unacceptable risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Moderate Concern to occupational health and safety under the conditions of the occupational settings described based on the irritant potential of imported polymer emulsion.

10.3.2. Public health

There is No Significant Concern to public health when used as indicated.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of imported product containing the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. 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, 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified polymer:

  R38: Irritating to skin;
  R41: Risk of serious damage to eyes

- Use the following risk phrases for products/mixtures containing the notified polymer:
  - $\geq$ 20%: R38
  - $\geq$ 10%: R41
  - 10% $\geq$ conc $\geq$ 5%: R36

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:

  - transfer of the imported emulsion should be carried out with mechanical aids to minimise manual handling.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Impermeable gloves, protective clothing, chemical goggles, industrial footwear.

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 in accordance with State/Territory waste management guidelines. Keep spills and cleaning runoff out of municipal sewers, stormwater or open bodies of water.
- Wastes generated during industrial application of paint products containing the notifier polymer should be disposed of through a licensed waste contractor.
- In domestic applications unused/unwanted paint should be kept in the original container and collected by Local Government programs for recycling and/or left to dry and sent to landfill. Paint wastes generated during domestic use should be disposed of according to the following instructions: "Do not pour leftover paint down the drain. Unwanted paint should be brushed out on newspaper, allowed to dry and then disposed of via domestic waste collections. Empty paint containers should be left open in a well-ventilated area to dry out. When dry, recycle steel containers via steel can recycling programs. Disposal of empty paint containers via domestic recycling programs may differ between local authorities. Check with your local council first."
- Overspray wastes on drop sheets should be allowed to dry and sent to landfill for disposal.

Emergency procedures

- Spills/release of the notified polymer should be contained with inert materials (eg. sand, earth). Transfer liquids and adsorbent material to labelled containers for recovery or disposal as described above.

12.1. Secondary notification

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

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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