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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Synthetic Resin TC

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Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

Synthetic Resin TC

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Degussa Coatings and Colorants Pty Ltd (ABN: 16 079 823 313)
30 Commercial Drive
DANDENONG VIC 3175

NOTIFICATION CATEGORY
Standard: Polymer with NAMW < 1000 (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

chemical name, CAS No., molecular and structural formulae, molecular weight, import volume, spectral data, purity, constituents, additives and adjuvants, means of identification, details of customer involvement, specific volumes for each market segment, names of analogous chemicals that are monomeric constituents of the notified polymer, references that refer to analogous chemicals which are monomeric constituents of notified polymer, toxicological data of some analogous chemicals

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

acute dermal toxicity, acute inhalation toxicity, eye irritation, skin sensitisation, repeat dose toxicity, chromosomal damage, fish toxicity, invertebrate toxicity, algal toxicity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
None.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Synthetic Resin TC

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	< 1000
Weight Average Molecular Weight (Mw)	< 1000
% of Low MW Species < 1000	> 50
% of Low MW Species < 500	< 50

SPECTRAL DATA

ANALYTICAL METHOD	Infrared (IR) spectroscopy.
Remarks	A reference spectrum was submitted.

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL	IR spectroscopy, Gel Permeation Chromatography

METHOD

3. COMPOSITION

DEGREE OF PURITY
High.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

A single hazardous monomer is present but not at levels which would render the notified polymer hazardous.

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

ADDITIVES/ADJUVANTS
None.

DEGRADATION PRODUCTS
None known.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None known.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer is to be imported as pellets in 25 kg paper sacks.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10 – 30	10 - 30	30 - 100	30 - 100	30 - 100

USE
Component of pigment dispersions for use in coatings to be applied to industrial structures, steelwork, metal surfaces in homes and timber surfaces and furniture.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS
Notifier.

TRANSPORTATION AND PACKAGING
The notified polymer will be transported in 25 kg paper sacks shrink wrapped on to pallets.

5.2. Operation Description

The notified polymer will be dissolved in solvents. Batch sizes are typically 1500 kg and the solution is run off into 200 L steel drums. The resin solution is then mixed into a pigment dispersion which is run through a bead mill and drummed off. Finally, the pigment dispersion is used in the manufacture of coatings via processes of pumping various components into a mixing vessel, mixing and then drumming off.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport workers	5	2 hours/day	6 days/year
Warehouse	>6	4 hours/day	40 days/year
Process Workers	3-4		
Intermediate Resin solution		30-40 minutes/day	40 days/year
Colourant		15-20 minutes/day	55 days/year
Quality Control	2		
Intermediate Resin solution		60 mins/day	55 days/year
Colourant		30 mins/day	55days/year
Maintenance and cleaning			
Intermediate Resin solution		2 hours/day	55 days/year
Colourant		3-4 hours/day	55 days/year
R&D/TS chemists	3-4	6 hours/day	12 days/year
Paint formulation using resin at sites other than notifier	As above	As above	As above
Paint formulation using colourant	30-40	Not known	Not known
Point of Sale Retail Workers	100-200	30-60 minutes/day	260 days/year
Professional Painters	>1000	4 hours/day	260 days/year
DIY Painters	>1000	2 hours/day	2-3 days/year

Exposure Details

Transport and Warehousing

The notified polymer will be transported from the dockside to the in notifier's site where it will be stored. At the notifier's site, the imported sacks may be repacked for sale to other paint formulators. Colourants containing the notified polymer that are manufactured at the notifier's site will also be transported to other paint manufacturers. Exposure during the transport, warehousing, repacking and distribution of the notified polymer and products containing the notified polymer is not expected, except in the event of an accident where the packaging is damaged.

Workers are expected to wear rubber gloves, dust masks, and safety goggles when handling the notified polymer as imported.

Blending of notified polymer into intermediate solution

The notified polymer will be blended to into 65% (w/w) solution of notified polymer in solvent, known as Intermediate Resin TC.

During the blending process, the solvents are weighed and added into a mixing pot. The pot is then transferred by forklift to a mixing station, where a hopper chute lid is clamped to the mixing pot. Bags of the notified polymer are moved from the storage area to the mixing vessel on pallets by forklift. The bags are raised to the hopper chute by a vacuum lifter and feed into the mixing pot. A fume extractor immediately above the hopper extracts any resin dust which may be generated. The mixing vessel will be enclosed. Once mixing is complete, the solution is sampled for QC testing. Following QC approval the batch is run off into 200L drums. Dermal and ocular exposure to the notified polymer may occur as result of drips and spills during the charging of the vessel, QC sampling and filling of drums. The dust of the notified polymer may be inhaled during the charging of the mixing pot. Workers are expected to wear rubber gloves, dust masks (if dust develops), and safety goggles if handling the notified polymer as imported. Staff undertaking QC testing will wear gloves and safety glasses. Workers handling the Intermediate Resin TC will wear overalls, goggles, and gloves. Fillers will wear safety glasses and gloves.

Colourant Manufacture using intermediate solution

Intermediate Resin TC solution is weighed out with other liquid components and added directly into the mixing pot. The mixing pot is then transferred to a mixing station. Pigments are added to the mixing pot via hopper chute and the components stirred in an enclosed system. The concentration of

the notified polymer in the dispersion will be 5 to 30%. The pigment dispersion is passed through a horizontal bead mill whereby the pigment is finely ground to specified strength and shade. The dispersion is sampled for QC testing by QC laboratory staff. The mix is then deaerated to remove the entrapped air and packaged into 1 L cans or 20 L pails via automated filling lines. Workers handling the Intermediate Solution TC will wear gloves, overalls, and safety glasses. Workers handling the colourant will wear gloves, goggles, and overalls. Dermal and ocular exposure to the notified polymer may occur as result of drips and spills during the charging of the vessel, QC sampling and filling of drums. Fillers will wear safety glasses, and gloves

Equipment maintenance.
Maintenance and cleaning of equipment used in blending the intermediate solution and the colourant will occur on a regular basis. Dermal and accidental ocular exposure to residual notified polymer may occur during the processes. Workers will wear gloves, safety glasses, apron and a respirator as required.

R&D and Technical Chemists
R&D and technical chemists will be involved formulation and testing of new colourants containing the notified polymer. These chemists will only use a small amount of notified polymer every day. Dermal and accidental ocular exposure to the notified polymer may occur as a result of drips and spills. Workers are expected to wear gloves, safety glasses, and laboratory coats.

Use of colourant in the manufacture of paints in plants
The colourants containing the notified polymer will be blended with paint bases in the manufacture of paints. Approximately 30% of the colourant produced will be used in paint manufacturing plants. In general, during paint manufacture the colourant and other components of the paint are weighed and mixed in large mixing vessels under slow speed and in well-ventilated areas. The final paints will contain <5% notified polymer. Dermal and ocular exposure to the notified polymer may occur as a result of drips and spills.

Use of colourant in the blending of the paints at the point of sale
The colourants containing the notified polymer will also be used at retails trade depots, to allow custom shades of paints to be produced as required. At these outlets, shop assistants will be fill canisters on dispersing machines, which release exact amounts of the colourant into paint base. The resultant paint is then mixed by shaking. The paint will contain approximately <5% concentration of the notified polymer. Dermal and ocular exposure may occur as result of drips and spills. Workers will wear gloves.

Use of the paints containing the notified polymer
Paints containing the notified polymer are expected to be sold to and used by the paint industry as well as professional and DIY painters. 80% of the paint is expected to used by spray paint applications and 20% by brush/roller applications. The bulk of the spray painting would be conducted at industrial sites using spray booths.

Industrial paint application
Exposure during industrial paint application may occur when the paints are mixed and sprayed and during the cleaning of the equipment.

The industrial paints will tend to be applied by spray, much of which will occur in booths, but some paints will be applied outdoors. In these instances, respirators will be worn.

Paint users will wear gloves, coveralls, and goggles (or safety glasses) and an effective filtered exhaust system will be used.

Architectural paint application
Exposure may occur when the architectural paint is applied and during the cleaning of equipment. Professional applicators will apply the coating by brush, roller, and sometimes by spray. Applications occur in largely uncontrolled conditions; controls may involve opening windows and wearing a respirator when spraying.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Release during manufacture of Intermediate Resin TC Solution

Loss during addition of the notified polymer to the mixing pot via a hopper chute is possible but unlikely as the bags are not open until they are resting on the hopper chute table. Any loss that drops to the floor would be swept up during regular housekeeping periods and placed into an industrial waste bin with other industrial waste destined for an approval landfill site. Spilt resin is unlikely to amount to any more than 0.25% which would represent an amount of 250 kg at the maximum import rate.

Release due to retention of the notified polymer in emptied bags - the physical form of the notified polymer is free flowing pale yellow pellets. It is estimated no more than 0.75% would be retained in the emptied bags which would represent an amount of 750 kg at the maximum import rate. Empty bags would be deposited in an industrial waste bin with other industrial waste destined for an approved landfill site.

Spillage of Intermediate Resin TC solution (containing 65% of the notified polymer) at filling stage: the intermediate resin solution is filled into 200 litre closed head drums. Spillage is possible but unlikely and would not be expected to amount to any more than 0.5% of production. This would amount to 500 kg per annum at the maximum import rate. Any spilt Intermediate Resin TC solution would be contained, collected into a suitable container and eventually sent to an approved waste disposal site, where waste is incinerated at a Flame temperature above 1 000ºC.

Release during manufacture of colourants at notifier's plant

Spillage of Intermediate Resin TC solution at weighing stage: any spillage is unlikely to amount to anymore than 0.5% of production. This would account for a maximum of 500 kg per annum at the maximum import rate. Spillage of colourant during premixing, milling or filling operations: once the Synthetic Resin TC has been mixed with all other components of the colourant then loss during the mixing, milling or filling stages would be unlikely and would only be due to mechanical mishap. Any spillage of colourant could largely be reclaimed by scooping up the spill, filtering and returned to the bulk of the product.

Any spillage from the line-filling machine is not reclaimable and would be contained, collected into a suitable container and eventually sent to an approved solvent waste incineration site. It is unlikely any loss due to spillage on average would amount to any more than 1 % of total production which would amount to a maximum of 1000 kg per annum at the maximum import volume.

Loss due to cleaning of mixing pots, bead mill and filling line machines: A 3% loss of colourant is allowed for these cleaning operations. At the maximum import rate (100 tonnes per annum) this will account for a loss of up to 3000 kg of resin. Solvents are used for cleaning the above equipment and the resultant contaminated wash solvent is stored in 200 litre drums and subsequently sent for incineration.

RELEASE OF CHEMICAL FROM USE

Colourants manufactured by the notifier will be supplied in either 1 litre or 20 litre containers to paint companies, either for use tinting at point of sale (P.O.S.) outlets or for in-plant tinting of paints. It has been estimated that 70% of the colourant supplied to the paint companies will be used at P.O.S. outlets and the other 30% for in-plant tinting of base paints.

Release at Paint Company Sites

In-plant tinting of paint relates to where paint companies use colourants for tinting their own paint base to attain specific colours. Such paints are subsequently sold to the paint trade and could contain up to 5% of the notified polymer.

Some accidental release could result due to accidental mishap resulting in damage to the colourant cans or tinted paint cans during transport to or from the paint company site but this is an unlikely scenario. In such cases, any spill would be contained, collected and disposed of, most likely by incineration at an authorised site.

In-plant tinting involves adding the colourant to the required paint base then mixing to the desired

shade before packing out into the can size required. An estimated 1.5% loss of the notified polymer could result from inadequate drainage of the colourant cans and 2.5% from cleaning of mixing vessels, stirrers and filling line equipment.

Assuming 30% of the polymer is used to produce colourants fro in house paint tinting at most approximately 450 kg of the notified polymer would be lost due to retention in the cans or pails which were supplied to the paint companies as colourant and 750kg of resin may be lost due to cleaning of equipment. These losses would be spread over sites in Vic, NSW and South Australia.

The residual amounts in the emptied cans would be allowed to dry before crushing and sending to an authorised land fill site whilst the amount of resin lost due to cleaning operations would most likely be incinerated at an approved site as waste solvent.

Release at Point of Sale Outlets
Tinting at P.O.S. stores infers individual cans of base paint can be tinted to the required shade by disposing a measured volume of colourant into the paint base and mixing by shaking. Customers may be professional painters or DIY painters.

Assuming up to 70% of the notified polymer is expected to be used as colourants at 50 or more P.O.S. Industrial Paint Store outlets throughout Australia. The amount of Synthetic Resin involved in these colourants would be approximately 70 tonnes at the maximum import volume.

The amount of colourant added to the paint base will vary with the shade required but for the basis of this notification will be assumed to be 15%. The colourants are added to the base paint from a dispensing unit which has a reservoir for each colourant required. The reservoirs, also known as canisters, are kept topped up with colourant to prevent them drying out on the sides of the canister but periodic cleaning of the dispenser nozzles is required.

Loss of the notified polymer from usage of colourants at P.O.S. outlets would result from cleaning of the canisters and inadequate drainage of colourants from the cans. It is estimated this could result in a loss of 3% of the notified polymer amounting to a loss of around 2100 kg (assuming a maximum of 60 tonnes of the imported polymer will be used for P.O.S tinting) of resin from the stores at which it will be used. Emptied cans would be allowed to air dry before crushing and sending to a metal recycling company or to an approved landfill site.

Overall up to approximately 7800 kg of the imported polymer will be disposed of either by incineration (~4500 kg) or to landfill (~3300kg) during the production of paints containing the notified polymer.

Release of the notified polymer Resulting from Use of Paint
Paints tinted with this resin are expected to be used by both professional and "Do It Yourself" (D.I.Y.) painters throughout Australia. It is estimated 80% of the paint will be used by Spray Painting application and 20% by Brush/Roller application.

Allowing for losses of Synthetic Resin incurred during the manufacture of the resultant paints which contain this resin, then at the maximum import volume paints available for use would contain approximately 92.2 tonnes of the resin.

Loss of the notified polymer from emptied containers of paint - loss of inadequate drainage of paint cans used in both spray and brush/roller applications could account for 1.5% of the volume of resin used which would amount to up to approximately 1383 kg of resin. This amount would be spread over all user sites throughout Australia. Emptied paint cans would be allowed to air dry before crushing and sending to a metal recycling company or to an approved land fill site. [The general recommendation for disposal of paint cans is to leave the emptied can in a well ventilated area to dry before disposal with household or industrial garbage to land fill or sending for recycling as part of a steel recycling program.]

Loss of the notified polymer due to Spray Paint Applications - the majority of spray painting is expected to be industrial based and conducted in correctly designed spray booths as described in AS/NZS 4114:1995 with risk minimization strategies as stated in NOHSC National Guidance Material for Spray Painting. The level of protection from exposure afforded by these standard protective

measures will provide more than adequate protection to the notified polymer as the resin is classified as a non-hazardous substance according to criteria of NOHSC.

Loss of paint due to overspray and cleaning could be as high as 40% which means –at the maximum import volume up to 30 tonnes (assuming that of the 92.2 tonnes of the polymer used in paints 80 % is applied using spray painting resulting in a 40% overspray) of resin could be lost to the environment. The overspray would be filtered out on the spray booth filter pads and residual solids, which would include the notified polymer, could be disposed of to an authorised land fill site. The loss of up to 33 tonnes of resin would be the representative total from all spray sites throughout Australia.

In cases where spray painting was conducted by D.I.Y. painters without control spray booth application then paint overspray could be released to the air, water or soil environment.

Loss of the notified polymer due to Brush/Roller Application – up to approximately 18.4 tonne of the notified polymer would be contained within paints destined for use by Brush/Roller application. Approx. 2.5% of this amount is expected to be lost to the environment due to cleaning of brushes, rollers, paint trays, etc which would amount to a maximum of approximately 460 kg of resin.

Paint companies discourage indiscriminate cleaning methods and for brush/roller users recommend to brush/roller excess paint onto old newspapers before washing the brush/roller in solvent. The newspaper should be allowed to dry before disposal via domestic waste collection.

Solvents such as mineral turps are then used for cleaning the brushes/rollers and the wash solvent retained & disposed of whenever hazardous waste programs are organised by local councils. Of the 460 kg of resin lost due to cleaning of brushes/rollers, it is estimated around 322 kg would be absorbed onto newspapers which would end up as land fill and 138 kg in waste solvent would be eventually incinerated.

However, given that the use paints containing the notified polymer will include DIY enthusiasts, there is potential for a portion of equipment cleaning wastes to be discarded into the sewer. Of the volume used domestically, approximately 80% or up to 18.4 tonnes will be applied by brush and roller by both DIY enthusiasts and professional applicators. It is estimated that approximately 5% or up to 920 kg may be disposed of to sewer as a consequence of improper disposal by DIY enthusiasts ie. through the washing of brushes/rollers with water.

Paints containing the notified polymer could be used by hundreds of DIY. painters, as well as professional painters, then the loss of the notified polymer will be shared by all user sites throughout Australia, resulting is a very dispersed waste generation profile.

5.5. Disposal

Waste polymer will either be incinerated or disposed of to landfill either as waste from manufacture of the pigment or paint products or as part of cured paint remaining in the drums or paint tins.

Total loss of the notified polymer to the environment due to manufacture and use of colourants and paints at the maximum import volume is estimated to amount to 35 tonnes of polymer. The majority of this (~33.3 tonnes) will be disposed of to landfill as residues from overspray and in containers. Some of the waste (4822 kg) is expected to be incinerated with the possibility that a small amount (960 kg) may be inappropriately disposed of to sewer.

5.6. Public exposure

The public is unlikely to be exposed to the notified polymer during transport, storage, manufacture and industrial and professional applications, except in the event of an accidental spill.

DIY enthusiasts who use the final architectural paints will be exposed. The likely routes of exposure would be dermal with possible accidental oral or ocular exposure. Inhalation exposure may occur if the paint is applied by spray. Due to the wide range of applications of the coatings in the domestic and industrial environments, public exposure via dermal contact with dried surfaces coated with paints and inks is also likely.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Pale yellow pellets.

Melting Point/Freezing Point 74-90ºC

METHOD DIN ISO 4625.
Remarks Test report not provided.
Source: Product Specification Data Sheet.

Density 1070 kg/m^3

METHOD DIN 51 479-B, ASTM D 2111.
Remarks Test report not provided.
Source: Product Specification Data Sheet.

Vapour Pressure Not determined.
Remarks The notified polymer is not expected to have a significant vapour pressure due to its polymeric nature. QSAR modelling of representative structures, ranging in molecular weight from 280-874, using the PBT profiler (www.pbtprofiler.net/), gave vapour pressures of less than 1.1×10^{-9} kPa indicating that the polymer is not likely to volatilise.

Water Solubility 10 mg/L at 21ºC

METHOD OECD TG 120 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Analytical Method: DOC

Test material was prepared by grinding the test substance with liquid nitrogen. In triplicate experiments, about 5 g of the test material was added to 500 mL (~10 g polymer/L) of purified water and shaken for 24 h at 21ºC to equilibrate. After filtration the dissolved organic carbon (DOC) was determined. The experiment was also repeated in triplicate at a concentration of around 1 g polymer/L and in a range of buffer solutions (pH values 2, 7 and 9). The pH 2 and 9 buffer solution tests were conducted at 20ºC and both gave a polymer concentration of 6 mg/L. The test conducted in the pH 7 buffer was conducted at 37 ºC.
TEST FACILITY Degussa (2003)

Hydrolysis as a Function of pH Not determined.

Remarks Determination of the hydrolysis as a function of pH (according to OECD guideline 111) was not attempted due to the low water solubility of the notified polymer. The notified polymer is not expected to hydrolyse in the environmental pH range (4-9).

Partition Coefficient (n-octanol/water) Not determined.

Remarks QSAR modelling of representative structures, ranging in molecular weight from 280-874, using the PBT profiler (www.pbtprofiler.net/), gave logPow values between 2.5 and 11. Although the latter value is unrealistically high the results indicate that the notified polymer is likely to partition to the organic phase.

Adsorption/Desorption Not determined.

Remarks The low water solubility and the estimated high partition coefficient for the notified polymer would indicate that it is likely to adsorb strongly to soils and sediments.

Dissociation Constant Not determined.

Remarks The notified polymer does not contain functional groups which will undergo dissociation.

Particle Size Pastilles of 0.5 – 1 cm.

Flash Point Not applicable.

Flammability Limits Not determined.

Autoignition Temperature > 390ºC

METHOD DIN 51 794

Remarks Test report not provided.
Source: Product Specification Data Sheet.

Explosive Properties Not determined.

Reactivity Stable.

Remarks Expected to be stable under normal environmental conditions.

7. TOXICOLOGICAL INVESTIGATIONS

There are limited toxicological data available for the notified polymer. Appropriate analogues were identified and used where data gaps existed.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 >2000 mg/kg bw (notified polymer)	low toxicity
Rat, acute dermal (KB4/KB3)	low toxicity
Rat, acute inhalation (KB4/KB3)	low toxicity
Rabbit, skin irritation (notified polymer)	non-irritating
Rabbit, eye irritation (appropriate analogue)	slightly irritating
Guinea pig, skin sensitisation - non-adjuvant test (appropriate analogue)	no evidence of sensitisation
Repeat dose toxicity (KB4/KB3)	no significant potential for toxicity
Genotoxicity - bacterial reverse mutation (notified polymer)	non mutagenic
Genotoxicity – *in vitro* (KB4/KB3)	non genotoxic
Genotoxicity – *in vivo* (KB4/KB3)	non genotoxic
Pharmacokinetic/Toxicokinetic studies (KB4/KB3)	The analogues are rapidly absorbed from the gastrointestinal tract and rapidly eliminated from blood. The analogues are reduced to alcohols and these are conjugated with glucuronic acid before excretion in urine and bile.
Developmental and reproductive effects (KB4/KB3)	low potential for reproductive and developmental toxicity.
Carcinogenicity (KB4/KB3)	no significant potential for carcinogenicity.

7.1. Acute toxicity – oral

TEST SUBSTANCE — Synthetic Resin TC Batch M230568

METHOD
- Species/Strain: Rat/Sprague Dawley.
- Vehicle: 1% natrosol.
- Remarks – Method: No significant protocol deviation.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5/sex	2000	0/10

- LD50: > 2000 mg/kg bw.
- Signs of Toxicity: No clinical signs of toxicity were observed during the observation period. Body weight gain during the observation period was considered within the normal range for the strain of rat.
- Effects in Organs: The macroscopic examination of the animals at the study termination revealed no organ abnormalities.
- Remarks – Results:

CONCLUSION — The notified chemical is of low toxicity via the oral route.

TEST FACILITY — ICP Firefly (2003a)

7.2. Acute toxicity – dermal

No test report was provided.

7.3. Acute toxicity – inhalation

No test report was provided.

7.4. Irritation – skin

TEST SUBSTANCE	Synthetic Resin TC Batch M230568
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White.
Number of Animals	3 females.
Vehicle	None.
Observation Period	4 days.
Type of Dressing	Semi-occlusive.
Remarks– Method	No significant protocol deviation.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	0	-	-
Oedema	0	0	0	0	-	-

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

Remarks - Results

CONCLUSION	The notified chemical is non-irritating to skin.
TEST FACILITY	ICP Firefly (2003b)

7.5. Irritation – eye

TEST SUBSTANCE	Appropriate analogue.
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/Small White Russian.
Number of Animals	3/sex.
Observation Period	10 days.
Remarks - Method	

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.89	3	8 days	0
Conjunctiva: chemosis	0.28	2	6 days	0
Conjunctiva: discharge	0	2	1 hr	0
Corneal opacity	0.5	2	48 hr	0
Iridial inflammation	0.06	1	24 hr	0

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

Remarks - Results

Scattered or diffuse to easily discernable translucent areas were observed in three animals for 24 hours. Easily discernable translucent areas were

observed in two animals for 48 hours. No corneal effect was observed n any animal at 72 hours.

At 24 hour only pronounced partial redness of the iris was observed in one animal. All iridial inflammation was resolved by 48 hours.

Slight to severe redness and swelling of the conjunctivae were observed in animals up to day 8. At day 10 no chemosis or redness was observed in any animal. Discharge was observed at 1 hour but was absent in all animals by 24 hours.

At day 10, all eyes were normal.

CONCLUSION — The analogous chemical is slightly irritating to the eye.

TEST FACILITY — Huls (1985)

7.6. Skin sensitisation

TEST SUBSTANCE — Appropriate analogue.

METHOD — OECD TG 406 Skin Sensitisation - Buhler method.

Species/Strain — Guinea pig/Dukin Hartley.

PRELIMINARY STUDY — Maximum Non-irritating Concentration:
topical: 100%

MAIN STUDY

Number of Animals — Test Group: 20 Control Group: 10

INDUCTION PHASE — Induction Concentration:
topical application 100%

Signs of Irritation — There were no signs of dermal irritation either in the test animals or in the control group 30 hours after treatment following each induction. The control animals treated with the vehicle also showed no skin irritation at these times

CHALLENGE PHASE

1st challenge — topical application: 100%

Remarks - Method

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		30 h	*54 h*
Test Group	100	0/20	0/20
Control Group	100	0/10	0/10

Remarks - Results — At 30 and 54 hours after challenge, no signs of irritation were found on either the test animals or those of the control group. The vehicle also induced no skin reactions on any animals of either the test group or control group.

CONCLUSION — There was no evidence of reactions indicative of skin sensitisation to the analogue chemical under the conditions of the test.

TEST FACILITY — (Huls, 1997)

7.7. Repeat dose toxicity

No test report provided.

7.8. Genotoxicity – bacteria

TEST SUBSTANCE	Synthetic Resin TC Batch M230568
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100, TA102.
Metabolic Activation System	Phenobarbital/β-naphthoflavone induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 1.0, 3.16, 10, 316, 1000 µg/plate. b) Without metabolic activation: 1.0, 3.16, 10, 316, 1000 µg/plate.
Vehicle	Ethanol.
Remarks - Method	No significant protocol deviations. A dose range finding study was conducted using TA100 and the notified polymer at 1, 10, 100, 1000, 2500 and 5000 µg/plate. At concentrations of 5000 and 2500 µg/plate marked precipitation was observed. At 1000 µg/plate slight precipitation was observed. There was no evidence of toxicity at any concentration since the background lawn was normal and no reduction in the background lawn around the colonies was observed. Based on the results 1000 µg/plate was selected as the maximum concentration for the main test.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>1000	>1000	-
Test 2		>1000	>1000	-
Present				
Test 1	>5000	>1000	>1000	-
Test 2		>1000	>1000	-

Remarks - Results	In the mutagenicity and confirmatory assays, no significant increase in the number of revertants was seen for any strain either in the presence or absence of metabolic activation. No precipitation or toxicity was observed. Appropriate positive controls were used and in all cases lead to a large increase in revertant numbers, confirming the sensitivity of test systems.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	ICP Firefly (2003c)

7.9. Genotoxicity – in vitro

No test report provided.

7.10 Genotoxicity – in vivo

No test report provided.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	ISO 10634.1995 (not seen)
Inoculum	Activated sludge from a domestic sewage treatment plant.
Exposure Period	24 d
Auxiliary Solvent	none
Analytical Monitoring	dissolved oxygen probe
Remarks - Method	The test material was cooled to –20 ºC in a freezer and crushed in a mortar and pestle. After grinding the material was sieved and the a duplicate samples of the fraction less than 100 µm were inoculated with sewage sludge. A reference test system and a blank were also prepared. Biodegradation was monitored by measuring the dissolved oxygen content of the test vessels over a 24 day period.

RESULTS

Test substance		*acetate*	
Day	*% degradation*	*Day*	*% degradation*
0	0	0	0
4	0.5	4	8
7	3.5	7	94
12	3.5	12	98
16	4.5	16	99
20	4.5	20	100
24	3.5	24	100

Remarks - Results	The acetate reference was 100 % degraded during the study period. The test material showed only 3.5 ± 1 % degradation during the study.
CONCLUSION	The notified polymer is not readily biodegradeable.
TEST FACILITY	Leeder Consulting 2003

8.1.2. Bioaccumulation

A discussion regarding the bioaccumulation potential of the notified chemical was not provided for this notification. Given that the polymer has a NAMW below 1000 and a low water solubility and high estimated log P, would have potential to bioaccumulate. However, the use pattern of the polymer will result in very limited exposure of the polymer prior to curing in inert paint matrices.

8.2. Ecotoxicological investigations

8.2.1. Acute/chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Synthetic Resin TC
METHOD	US EPA 1993
Species	*Ceriodaphnia cf dubia*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	not reported

Analytical Monitoring	None
Remarks - Method	All concentrations are nominal and were based on a range finding test. Each test treatment was prepared separately in 500 mL borosilicate glass volumetric flasks, and stirred for 24 h at ambient temperature. It was noted that the test material failed to completely dissolve at concentrations above 10 mg/L. The undissolved test material floated on the surface of the test media in clumps. The test was conducted with 4 replicates of 5 animals. Test organisms did not appear to come into contact with the undissolved material.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	20	0	0
1	-	20	0	0
3	-	20	0	0
10	-	20	0	0
30	-	20	0	3
100	-	20	2	9
300	-	20	2	11

LC50	180 mg/L (108-411 mg/L 95% CI) at 48 hours
NOEC (or LOEC)	30 mg/L at 48 hours
Remarks - Results	Test was conducted well above water solubility and results appear to reflect a physical effect despite the above observations.
CONCLUSION	The notified polymer is practically non-toxic to ceriodaphnia under the test conditions.
TEST FACILITY	Ecotox Services (2004)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The majority of the notified polymer will be incorporated into paints and, once applied and dried poses little risk to the environment. During paint production up to 7800 kg per annum of waste containing the notified polymer will be generated from cleaning up minor spills, during the cleaning of formulation equipment, the disposal of import drums and the tinting of paints (both in house and at point of sale). It is possible some of the pigments containing the notified polymer manufactured may be exported.

Given that this product will be used by 'Do-it-Yourself' enthusiasts, there is potential for a portion of equipment cleaning wastes to be discarded into the sewer. Of the volume used domestically, approximately 80% or up to 18.4 tonnes will be applied by brush and roller by both DIY enthusiasts and professional applicators. It is estimated that approximately 5% or up to 920 kg may be disposed of to sewer as a consequence of improper disposal by DIY enthusiasts ie. through the washing of brushes/rollers with water. Release to sewer is expected to be low and diffuse due to the low content of the polymer in paint.

At the end of their useful lives, surfaces to which the paint has been applied will either be disposed of to landfill or incinerated.

Up to 80% (or up to 80 tonnes) will be applied by spraying. Assuming up to 40% overspray, close to 30 tonnes of the notified polymer will be wasted. This will be captured by engineering controls, dried and disposed of to landfill.

The notified polymer is not expected to be soluble in water and as such is likely to be immobile

in both aquatic and terrestrial compartments. In landfill as a consequence of its low water solubility, it is expected to associate with soil slowly degraded through biotic and abiotic processes to water and oxides of carbon and nitrogen and phosphorous salts. When introduced into the sewer the notified polymer is expected to be removed from the aquatic compartment and degrade slowly via the processes described above.

In landfill, the solid wastes are expected to be immobile, and eventually degrade through biotic and abiotic processes, and consequently, should not pose a significant exposure hazard to the environment.

Although the NAMW of the notified polymer is below 1000, and therefore potentially able to cross biological membranes, a limited amount of the notified polymer will be released to the environment which is not bound within the cured paint matrix. Hence, bioaccumulation is not expected due to the notified limited environmental release of the notified polymer.

9.1.2. Environment – effects assessment

The notified chemical is practically non-toxic to daphnia with an EC50 of 180 mg/L.

Acute results are available for only 1 trophic level. Applying an assessment factor of 1000 to the ecotoxicity data, the predicted no effects concentration (PNEC) is 0.18 mg/L.

9.1.3. Environment – risk characterisation

Waste polymer from reformulation into pigments/paints or residues in containers (either polymer transport drums or paint tins) will be disposed of to landfill as an inert solid or incinerated. Incineration of the polymer would destroy the material with the production of water vapour, and oxides of carbon and nitrogen.

The majority of waste polymer generated during manufacture (through spills and washing) will be disposed of in landfill

Accidental or intentional release to sewer is a possibility, with a maximum of 920 kg per annum potentially finding its way into the sewer. As a consequence of its low expected water solubility, the notified polymer will associate with sediment.

Assuming as a worst case that all 920 kg remains suspended in the sewage system the concentration in the sewer would be 0.65 µg/L (based on an Australian population of 20.1 million using 200 L per person per day). Thus the PEC/PNEC ratio is much less than 1 (0.0006/0.18 = 0.003). Hence, the limited exposure of the polymer to the aquatic compartment indicate that the polymer is unlikely to have an adverse effect on aquatic organisms.

The majority of the notified polymer will be applied to surfaces and either share the fate of the surface at the end of its useful life (most likely to landfill) or be removed by sanding. If removed by sanding the coating containing the notified polymer will be broken up into solid particulate matter and most likely disposed to landfill.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

During the repacking of the imported notified polymer, manufacture of the intermediate solution and colourant, dermal and ocular exposure as result of drips and spills can occur when opening containers, weighing and charging individual ingredients into a mixing vessel. Dust formed by the notified polymer may also be inhaled during the charging of the mixing vessels. However, exhaust ventilation is in place during the solution and colourant manufacture will limit inhalation exposure. There will be limited exposure to the notified polymer during blending solution and colourant as these processes will be enclosed. Limited exposure is also expected during filling and packing operations since these activities are carried out in an automated equipment. Personal protective equipment (PPE) includes impervious gloves, overalls, eye protection and dusk masks (as required) will be used when carrying out the above activities. The PPE is required to limit exposure to the solvents in the intermediate solution and colourant will preclude significant exposure to the notified polymer.

Exposure to small amounts of the coating mixture by the laboratory workers is minimised by wearing laboratory coats, gloves and eye protection.

Dermal and limited ocular exposure can occur during plant paint manufacture, point of sale tinting and paint application as result of drips and spills. During architectural paint application there is potential for worker exposure as these situations are uncontrolled other than by outdoor use or by opening windows. In most cases, industrial paint application is expected to applied by spray. Much of this expected to occur in booths but it is likely that some will be applied outdoors. In such instances, the workers will use respirators

Limited dermal and ocular exposure is possible when carrying maintenance work and the cleaning of equipment after coating formulation and paint application. Workers undertaking cleaning and maintenance would wear gloves, safety glasses, coveralls and respirators as required.

The notified polymer will be transported and stored in sealed sacks. While products containing the notified polymer will be transported and stored in sealed containers. Transport and storage workers are unlikely to be exposed to the notified polymer except in the event of accident.

9.2.2. Public health – exposure assessment

Public exposure will be limited to DIY enthusiast using the architectural paints. The main route of exposure will be dermal, with possible accidental oral and ocular exposure. Inhalation exposure may occur if the architectural paints are sprayed.

The public may make dermal contact with surfaces containing the dried coatings and printed surfaces, however, the polymer is firmly attached to the surface and not available.

9.2.3. Human health - effects assessment

The most commonly observed pathologic effect in both subchronic and chronic studies with linear and branched chain aliphatic and alicyclic ketones in KB3/KB4 mixtures is the appearance of hyaline droplet nephropathy in male rats. These reported renal pathologies, are not considered relevant to human health. Therefore it was concluded that exposure to low levels of ketones in KB4/KB4 provides no significant potential neurotoxicity or carcinogenicity (Eastman, undated). The major concern for chronic exposure to ketones is development of axonal neuropathy with secondary myelin damage, usually manifested as paresthesia and muscle weakness. However, only six carbon, linear chain ketones metabolised to gamma-diketones have been implicated (Meditext, 2003).

No significant reproductive effects were observed in reproductive/development studies for appropriate analogues. These analogues exhibited a low potential for developmental toxicity in development toxicity testing (Eastman Chemical Company, undated).

The notified polymer has low acute oral toxicity, is not a skin irritant, and was found not be mutagenic in a bacterial reverse mutation test. Based on its molecular weight the notified polymer would have limited ability to cross biological membranes. The analogue data supplied indicate that the notified polymer is likely to have low acute dermal and inhalation toxicity and not be a skin sensitiser. The notified polymer may be slightly irritating to eyes. The notified polymer is also likely to have no mutagenic or genotoxic potential The repeated dose toxicity studies, indicate that the notified polymer is unlikely be carcinogenic and have low reproductive and developmental toxicity potential.

9.2.4. Occupational health and safety – risk characterisation

The notified polymer is imported as large pellets and hence dust formation is expected to be minimal. As part of the water solubility tests, the notified polymer was ground into small particles and the particle size determined. Nineteen percent of the particles had a size less than 125 μm and represent the likely inspirable fraction. Particles with aerodynamic diameter of below 100 μm are assumed have the potential to be inhaled. During the manufacture of the 65%

intermediate resin solution of the notified polymer, dust formed during emptying of the 25 kg sacks into the mixer will be removed by local exhaust ventilation. The physical form of the notified polymer should preclude significant dermal exposure and use of nitrile gloves when handling it is recommended. The intermediate resin solution is drummed off into 200 L drums. Precautions required for handling the solvent should limit exposure to the notified polymer at this point.

The solvent solution is used to manufacture colourant by mixing of ingredients following processing through a bead mill for 8 – 12 hours. Dermal exposure may be possible when adding the solvent solution to the mixing vessel but the hazard of the solvent necessitates good work practices and adequate PPE. The colourants containing 5-30% notified polymer are transported in 20 L pails to paint manufacturers for addition to paints and to paint trade shops. Worker exposure during paint (<5% notified polymer) manufacture is will be limited by the use of good work practices and PPE in addition to largely automated and enclosed systems. Worker exposure at the point of sale tinting is likely and therefore safety glasses and gloves should be worn.

During the industrial coating application dermal, ocular and inhalation (if spraying) exposure to up to <5 % notified polymer may occur. In the industrial situation, spray coating application will occur in controlled situations, where adequate ventilation and PPE. However, in uncontrolled situations such as the use of architectural paints, workers should have adequate ventilation or use respirators.

9.2.5. Public health – risk characterisation

The paints containing the notified polymer are expected to sold and used in the paint industry and professional and DIY painters. The concentration of the notified polymer in these paints will be approximately <5%. It is estimated that 100 to 1000's of DIY painters would exposed to the notified chemical. The notifier has suggested that DIY workers will be exposed to notified chemical a 2 hours per day for 2-3 days per year.

The public will also be exposed to dry painted surfaces but the notified polymer will be not be available for absorption under these conditions.

While the notified polymer has low acute toxicity and the molecular size may restrict absorption. Due to the absence of repeated dose study for the notified polymer there is insufficient information to determine public health risk following repeated exposure. However based on the analogue data provided, it is expected that the public health risk would be low.

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

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

The notified polymer could not be classified using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003). This system is not mandated in Australia and carries no legal status but is presented for information purposes.

10.2. Environmental risk assessment

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

10.3.2. Public health

There is Negligible Concern to public health when used as described in the notification statement.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of 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, 1994a). 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 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.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced, as diluted for use, in the colourants:
  - Exhaust ventilation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced, as diluted for use, in the colourants:
  - Minimise drips and spills.
  - Avoid contact with eyes.
  - Use of spray paints containing the notified polymer should be accordance with the NOHSC National Guidance Material for Spray Painting (NOHSC, 1999b)

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced, as diluted for use, in the colourants:
  - Gloves, eye protection and dust mask (for handling notified polymer as imported)

  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 chemical 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.

Environment

Disposal

- Once dry, solid waste containing the notified polymer should be disposed of in landfill or by incineration.

Emergency procedures

- Spills/release of the notified polymer should be contained as described in the MSDS (ie. Collect spilled material with an inert absorbent) and the resulting waste disposed of to an authorised landfill.

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(1) of the Act; if
- information on toxicity and ecotoxicity studies conducted on the notified polymer becomes available
- the use pattern of the notified polymer changes in such a way as to result in an increase in the aquatic exposure. In such circumstances the secondary notification must include ecotoxicity data for both fish and algae.

or

(2) 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.

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