File No: NA/922

January 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Anti-Terra-204 WS

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, National Occupational Health and Safety Commission, Plaza level, Alan Woods Building, 25 Constitution Avenue, Canberra ACT 2600 between 9 AM and 5 PM Monday to Friday.

Copies of this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

For enquiries please contact the Administration Section at:

Street Address: 92 -94 Parramatta Rd CAMPERDOWN NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA
Telephone: (61) (02) 9577 9514 FAX (61) (02) 9577 9465

Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

Anti-Terra-204 WS

1. APPLICANT

Nuplex Industries (Aust) Pty Ltd of 49-61 Stephen Road, BOTANY NSW 2019 (ACN 000 045 572) and Degussa Coating & Colorants Pty Ltd of 30 Commercial Drive DANDENONG VIC 3175 (ABN 16 079 823 313) have submitted a standard notification statement in support of their application for an assessment certificate for 'Anti-Terra-204 WS'.

2. IDENTITY OF THE CHEMICAL

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

Marketing Name: Anti-Terra-204 WS,
Anti-Terra 204 (product containing the notified polymer),
868-7214 Alkydtrend Phthalo Blue E (product containing the notified polymer).

3. PHYSICAL AND CHEMICAL PROPERTIES

Data of physical and chemical properties were generated from the notified polymer.

Appearance at 20°C & 101.3 kPa: A non volatile light amber coloured viscous liquid

Melting Point: <-50°C

Boiling Point: 245°C

Density: 956 kg/m^3 at 20°C

Vapour Pressure: < 0.01 kPa at 20°C

Water Solubility: < 10 mg/L at 20°C

n-Octanol solubility > 400 g/L

Partition Co-efficient

(n-octanol/water):	Not determined.
Hydrolysis as a Function of pH:	Not determined.
Adsorption/Desorption:	Not determined.
Dissociation Constant:	The notified polymer is not expected to dissociate in water as it is insoluble in water.
Particle Size:	Not determined, exists in liquid form.
Flash Point:	> 100°C
Flammability Limits:	Not determined.
Autoignition Temperature:	Not determined.
Explosive Properties:	Not determined.
Reactivity/Stability:	No decomposition occurs up to 250°C

3.1 Comments on Physico-Chemical Properties

The vapour pressure of the notified polymer was determined using the static method detailed in the OECD TG 104 (Springborn Laboratories, 1999a). The vapour pressure was determined to be less than 10 Pa at 20ºC which classifies the notified polymer as moderately volatile.

The water solubility was determined using a modified flask method according to OECD TG 105 (Springborn Laboratories 1999b). To each of three 500 mL round bottom flasks (RBF) was added the notified polymer (25 mg) and distilled water (200 mL). The RBFs were placed on an incubator/shaker and shaken at 100 rpm at 30 ºC. Flask 1, flask 2 and flask 3 were shaken for 24, 48, and 72 h, respectively. All three flasks were than shaken for another 24 h at 100 rpm at 20 ºC, centrifuged at 2 500 rpm for 15 min and the supernatant analysed. This method indicated that the solubility of the notified polymer is < 10 mg/L. However, based on the detection limit this should actually be less than 1.15 mg/L. Another study is said to have indicated a solubility of less than 0.224 mg/L and as indicated in the toxicity studies the DOC concentration of saturated solutions of the notified polymer are between 1.5 and 2.9 mg/L.

The partition coefficient has not been determined due to the notified polymer's water insolubility, and its apparent hydrophobic nature, indicative of partitioning into the *n*-octanol phase. The notifier indicated the *n*-octanol solubility of the notified polymer is greater than 400 g/L (Springborn Laboratories, 1999c). The notifier indicates that based on the notified polymer's solubility in water and *n*-octanol, the log K_{ow} for the notified polymer is approximately 6.2. This indicates that the notified polymer is very hydrophobic.

The notified polymer contains amide linkages that could be expected to undergo hydrolysis under extreme pH conditions. However, in the environmental pH range of 4 to 9, significant hydrolysis of these is unlikely to occur.

The notifier indicates that no adsorption/desorption tests were conducted because of the polymer's limited solubility in water. As a consequence of its cationic nature and low water solubility, the notified polymer is expected to associate with the soil matrix and sediments and as such will be immobile in soil.

No dissociation constant tests were conducted for this polymer although it is fully ionised. Presumably this was due to the low solubility. The notified polymer is expected to dissociate at higher pH.

4. PURITY OF THE CHEMICAL

Degree of Purity: High.

Additives/Adjuvants:

Chemical name:	Petroleum solvent
Synonyms:	Naphtha
CAS No.:	64742-95-6
Weight percentage:	>10
Toxic properties:	May cause cancer (carcinogen category 2, Toxic only if benzene content is >0.1%); Harmful: May cause lung damage if swallowed (NOHSC, 1999a).

5. USE, VOLUME AND FORMULATION

Anti-Terra 204 WS is a polymeric dispersing additive for use in solvent based paint applications. Anti-Terra 204 containing approximately 50% of the notified polymer will be imported into Australia in 200 L steel drums. Up to 6 tonnes per year will be imported in the first 5 years.

Nuplex Industries will formulate Anti-Terra 204 into a bentonite paste product at 1-3%, or a paint product at <0.7%. These products will be used as anticorrosive paints and primer surfaces for refinishing paints used in cars. The packaging for the solvent based paint will be 20 or 200 L steel pails or drums.

Degussa Coating & Colorants will formulate Anti-Terra 204 into a Medium-oil Alkyd based pigment dispersion containing less than 2% notified polymer in 4 or 20 L cans, and supply the pigment dispersion to both Australia and international market. In Australia, paint manufactures will use this dispersion for the tinting of alkyd and oleoresinous trade solvent thinned paints and nitrocellulose lacquers such as sash and trim paints, oil based house paints, gloss and semi-gloss enamels, alkyd flats, oleoresinous paints, wood stains and nitrocellulose. Concentrations of the notified polymer in the final painting products are less than 0.08%. The notifier estimates that approximately 70% products containing the notified polymer is expected to be used in industrial spray painting on steel components and automotive parts,

and the other 30% will be used by roller/brush application used by both professional and DIY painters.

6. OCCUPATIONAL EXPOSURE

6.1 Occupational exposure from the Nuplex Industries Pty Ltd products.

Nature of Work	*Number of Workers*	*Maximum Duration of Exposure (Hours/day)*	*(Days/year)*
Transport and warehouse personnel	10		200
Paint and bentonite paste manufacture			
High speed dispersing	40	4	30
Makeup	40	2	30
QC testing	10	8	30
Packaging	40	8	30
Paint application			
Preparing painting	10	8	200
Spray painting	20	8	200
Cleaning	30	2	200

Transport & storage
Anti-Terra 204 containing approximately 50% notified polymer will be imported into Australia in 200 L steel drums. Since the notified polymer is imported in sealed drums, waterfront, transport and warehouse workers are not expected to be exposed to the notified polymer except in the case of an accident involving spillage of the polymer solution.

Formulation
Anti-Terra 204 will be formulated into a bentonite paste product at 1-3%, or a paint product at <0.7%. Three groups of workers will be involved in the process; in high speed dispersing, makeup and quality control, and packaging. The mixers used for preparing the paint are enclosed and fitted with local exhaust ventilation. Dermal exposure to the notified polymer will be possible at several points throughout the process; charging the polymer solution into the mixer, removal and testing of samples for quality control, and drips and spills during paint filtration and filling. The formation of aerosols during the high speed mixing will be unlikely because of the viscosity of the mixture.

The mixing and filling will be carried out under local exhaust ventilation to prevent exposure to the solvents. Workers will wear impervious gloves, coveralls and goggles, with additional personal protective equipment being used as required.

Laboratory development and testing with both the paint and paste products are performed by the makeup and quality control workers. Exposure would be by skin contact during the handling of small quantities of the polymer solution and paint. Worker exposure to the notified polymer and other paint ingredients in the laboratory environment is controlled through the use of ventilated fume cupboards and personal protective equipment consisting of coveralls/laboratory coats, impervious gloves and eyewear.

Paint Application

The spray painters who will be exposed to the notified polymer will be fully TAFE trained. Typically the spray painter will measure the appropriate amounts of the different components required in a particular formulation into an open container and pour this mixture into a spray gun. The spraying of the automobile will be carried out in a laminar flow downdraft spray booth which is designed to rapidly remove aerosol particles and solvent vapour from the atmosphere. Several possible booth designs may be used. In a dry floor booth, the overspray will be collected in filters contained in the floor of the booth; any unremoved particulates will reach the exhaust stack with the solvent vapours. In a wet floor booth, overspray will collect in a pool of water below the grill floor or in a wet scrubber in the exhaust and will be removed with a filter. The residual solids will be disposed of to secure landfill. The spray booths are subject to AS/NZS/4114.1:1995 *Spray Painting Booths – Design, Construction and Testing* and AS/NZS/4114.1:1995 *Spray Painting Booths – Selection, Installation and Maintenance*. After application of the paint, the automobile are heated to cure the coating.

Residual paint mixture is likely to be washed from the equipment manually, using recycled paint solvent, and the washings disposed of by solvent recyclers.

Once the final paint mixture has dried, the notified polymer will be irreversibly bound within the cured matrix and not separately available for exposure to workers.

Spray painters will wear appropriate personal protective equipment at all times; impervious gloves and anti-static flame retardant overalls while mixing the paint, and, in addition, a full face shield and respirator conforming to AS/NZS1715 and AS/1716 while inside the spray booth.

6.2 Occupational exposure from the Degussa Coating & Colorants Pty Ltd products.

Nature of Work	*Number of Workers*	*Exposure*
Transport and warehouse personnel	90	
Colorant dispersion manufacture		
Process worker	2	6 hr/day, 32 days/year
Filling and packaging	2	3 hr/day, 16 days/year

QC testing	2	1 hr/day, 16 days/year
Technical service/development	4	250 days/year
Paint products manufacture	100-200	
Paint application		
Spray application	50-100	4 hr/day, 250 days/year
Roller/brush application	Not provided.	

Transport & storage
There will be 3 storeman at the notifier's plant handling Anti-Terra 204 in 200 L steel drums, 50 storeman across Australia handling colorant dispersion in 4 or 20 L containers, and 30-40 dock and transport workers handling the final paint products for export. These storeman will not be exposed to the notified polymer except in the event of spillage.

Colorant dispersion manufacture
Workers at the colorant dispersion manufacture site could be exposed to the notified polymer during weighing out and adding them into a mixing pot. The process workers will directly handle the notified polymer for approximately 10 minutes a day, although their presence at the workshop is 6 hours per day.

After mechanical agitation, the mixture is circulated through a bead mill to finely grind and disperse the pigment to the correct particle size to obtain the correct colour strength and shade. The concentration of the notified polymer in the colorant dispersion is less than 2%. At this stage, workers will have no direct contact with the notified polymer apart from ensuring the bead mill is operating properly and there are no leakages.

The QC staff will handle only small amount of sample for analysis. The R & D chemists could be involved in experimental work on colorants containing the notified polymer, and technical service chemists may need to use samples containing the notified polymer when conducting colour matching.

After QC testing, the colorant dispersion will be packaged into 4 or 20 L steel pails. An automatic filling and labelling machine will be used for the 4 L containers. The 20 L pails will be filled from the mixing pot by gravity feed.

One operator will clean the mix pot and the filling lines on daily bases. Solvent is used in the washing process, and the waste solvent is retained for appropriate waste disposal. This operator would be exposed to the colorant dispersion containing <2% notified polymer for 2 hours per day and 16 days per year.

Dermal exposure to the notified polymer may occur during weighing, adding the polymer solution into the mixer, removal and testing of samples for quality control, drips and spills during packaging, and cleaning process. Eye contamination is possible. The formation of

aerosols will be unlikely because of the viscosity of the mixture. The notifier states that the colorant dispersion manufacture site is a strictly controlled solvent plant area where many similarly classified flammable and hazardous solvents are used. Explosion proof ventilation equipment is fitted. If mist generates, an approved half-face filter respirator suitable for organic vapours will be used. Process workers will wear chemical resistant gloves, appropriate half mask respirator and safety glasses of goggles.

Formulation
Occupational exposure information at the formulation sites is expected to be similar to that provided by Nuplex Industries Pty Ltd.

After formulation, the final paint products will contain less than 0.1% notified polymer.

Paint Application
Approximately 70% paint products containing the notified polymer will be used for spray painting by the professional sprayers. The notifier states that there are 10-20 spray panting sites throughout Australia. Occupational exposure to the notified polymer at the spray painting sites is expected to be similar to that provided by Nuplex Industries Pty Ltd.

Professional painters and DIY painters will use the other 30% paint products by roller/brush application. Dermal contamination is still the main route for occupational exposure. Inhalation exposure is unlikely during roller and brush application. The professionals wear overalls during their work. Because of the low concentration of the notified polymer in the final paint products, the exposure is considered to be low.

Once the final paint mixture has dried, the notified polymer will be irreversibly bound within the cured matrix and not separately available for exposure to workers.

7. PUBLIC EXPOSURE

Public contact with the notified polymer, either as the pure viscous liquid or as a component of coatings, is possible following transport accidents. Contact with the notified polymer as an environmental contaminant is also unlikely since it does not readily disperse or accumulate in the environment. The coatings are applied under controlled conditions in processing plants. The notified polymer becomes incorporated into a heat cured inert film on the finished article. In this form it is inaccessible to human contact. The potential for public contact with the notified polymer is therefore minimal. A small proportion of DIY painters may be infrequently exposed to paints containing <0.08% notified polymer.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

During coatings production, the notifier estimates that up to 50 kg per annum of waste containing the notified polymer will be generated from cleaning up minor spills and cleaning out manufacturing equipment. The notifier further estimates that up to 3.5 tonnes per annum of the notified polymer will be disposed of during coating use and up to 100 kg of the notified polymer will be disposed of during drum cleaning.

8.2 Fate

The majority of the notified polymer will be combined with other paint components to form a very high molecular weight and stable paint film. Therefore, once incorporated into the paint formulation, the notified polymer is expected to be immobile and pose little risk to the environment. As the coating degrades over time, any fragments, chips and flakes of the lacquer will be of little concern as they are expected to be inert. The metal panels and car bodies coated with the polymer are likely to be either recycled for steel reclamation or be placed into landfill at the end of their useful life. When recycled the polymer would be destroyed in furnaces and converted to water vapour and oxides of carbon

A biodegradation study was conducted according to OECD TG 301E; modified OECD Screening Test (BioChem GmbH, 1996a). The inoculum was obtained from Neureut sewage treatment plant in Karlsruhe, Germany. Two saturated solutions were prepared by adding the notified polymer (~2 g) to each of two flasks containing mineral medium (1 L) and shaking these flasks overnight. Following filtration the DOC of the clear solution was determined to be 8.8 mg DOC/L (bottle 1) and 39.6 mg DOC/L (bottle 2). The biodegradation of the notified polymer was compared against sodium benzoate and sodium acetate trihydrate. The biodegration of sodium benzoate and sodium acetate trihydrate was 97 and 82%, respectively after 28 days, indicating the test conditions were valid. After 28 days at 21 °C, the biodegradation of the test substance was determined to be 66%, but note that 79% biodegradation was achieved after 16 days. The notified polymer failed to satisfy the 10 day window criterion whereby 70% degradation must be attained within 10 days of the degradation exceeding 10%. However, despite the low apparent rate for biodegradation, it is expected that if placed into landfill the material would be slowly degraded through the slow biological and abiotic processes operative in these facilities. These processes could be expected to produce carbon dioxide, methane and water.

The notified polymer in waste from spills, equipment cleaning and drum recycling will be collected by licensed waste disposal contractors and treated by a distillation process whereby, the solvent is reclaimed and the remaining solid containing the notified polymer will be disposed of in landfill. The notified polymer in overspray will also be disposed of in landfill. The notifier indicates that incineration of waste may also occur.

The notified polymer is not water soluble and therefore will not be mobile in either the terrestrial or aquatic compartments. As a consequence of its cationic nature and low water solubility, the notified polymer is expected to eventually associate with the soil matrix and sediments. The notified polymer is not expected to cross biological membranes due to its high molecular weight and low water solubility and is therefore not expected to bioaccumulate (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Anti-Terra-204 WS

Test	*Species*	*Outcome*	Reference
acute oral toxicity	rat	LD50>10 g/kg	Pharmatox GmbH, 19985a
acute dermal toxicity			Variation sought
skin irritation	rabbit	Slight irritant	Pharmatox GmbH, 19985b
eye irritation	rabbit	Slight irritant	Pharmatox GmbH, 19985c
skin sensitisation			Variation sought

9.1.1 Oral Toxicity (Pharmatox GmbH, 1985a)

Species/strain:	Rat/SPF-Wistar
Number/sex of animals:	5 sex/dose
Observation period:	14 days
Method of administration:	Oral by gavage at 5 and 10 g/kg. Vehicle: Cellulose, carboxymethyl ether (CMC) and Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivatives (Tween 20).
Test method:	OECD TG 401
Mortality:	None.
Clinical observations:	None.
Morphological findings:	None.
Comment:	GLP statement was provided but not a QA statement.
LD_{50}:	>10 g/kg.
Result:	The test material was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity

The notifier applied variation for acute dermal toxicity study.

9.1.3 Inhalation Toxicity

The notifier applied variation for acute inhalation toxicity study.

9.1.4 Skin Irritation (Pharmatox GmbH, 1985b)

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 5 (did not specify sex)

Observation period: 7 days

Method of administration: A dermal dose of 0.5 g notified polymer (50% in CMC and Tween 20) was applied under an occlusive dressing to intact and abraded skin areas for 24 hours.

Test method: OECD TG 404

Draize scores:

	Animal #									
Time after treatment (days)	***1***		***2***		***3***		***4***		***5***	
	intact	***abraded***	***intact***	***abraded***	***intact***	***abraded***	***intact***	***abraded***	***intact***	***abraded***
Erythema										
1	[a]0	1	0	0	0	1	0	1	0	1
3	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0
Oedema										
Draize scores for oedema were zero for all animals during the study.										

[a] see Attachment 1 for Draize scales

Comment: The treatment time was 24 hours in this study, and 48 hour readings were not provided.

GLP statement was provided but not a QA statement.

Result: The test material was non-irritating to the skin of rabbits.

9.1.5 Eye Irritation (Pharmatox GmbH, 1985c)

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 6 (did not specify sex)

Observation period: 7 days

Method of administration: A dose of 0.1 mL (50% in CMC) was applied to conjunctival sac of one eye. The untreated eye served as the control.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

				Time after instillation			
Animal	***1 hour***			***2 hours***			***4, 8, 24 hours and 2, 3, 4,5, 6, 7 days***
Cornea							
	Draize scores for cornea (opacity and area) were zero for all animals during the study.						
Iris							
	Draize scores for iris were zero for all animals during the study.						
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	
1	1	0	1	1	0	1	Draize scores for conjunctiva (redness, chemosis and discharge) were zero for all animals from 4 hour to day 7.
2	1	0	1	1	0	1	
3	1	0	1	1	0	1	
4	1	0	1	1	0	1	
5	1	0	1	1	0	1	
6	1	0	1	1	0	1	

[1] see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge

Comment: GLP statement was provided but not a QA statement.

Result: The test material was slightly irritating to the eyes of rabbits.

9.1.6 Skin Sensitisation

The notifier applied for variation for skin sensitisation study.

9.2 Repeated Dose Toxicity

The notifier applied for variation for repeat dose toxicity study.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Springborn Laboratories, 1999d)

Strains:	*S. typhimurium* TA98, TA100, TA102, TA1535 and TA1537
Metabolic activation:	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254.
Concentration range:	Triplicate plates were prepared for each bacterial strain and dose level, in both the presence and the absence of S9-mix. Ethanol was used as the vehicle. Definitive and independent repeat tests: 0, 0.5, 5, 50, 500 and 5 000 μg/plate in all strains with or without S9-mix. Negative control: (without S9-mix) Ethanol alcohol and DMSO for TA98 and TA1537; Ethanol alcohol and water for TA100, TA102, and TA1535. (with S9-mix) Ethanol alcohol and DMSO for all strains. Positive controls: (without S9-mix) • 2-nitrofluorene for TA98; • sodium azide for TA100 and TA1535; • Mitomycin C for TA102; • 9-aminoacridine for TA1537. (with S9-mix) • 2-aminoanthracene for all strains.
Test method:	OECD TG 471
Comment:	Some cytotoxicity at 5 000 μg/plate was observed in the preliminary study, but not in the definitive and independent repeat studies. Under the conditions of the study, the notified chemical caused no substantial increases in revertant colony numbers over control counts at any concentration in either the presence or absence of the rat liver microsomal enzymes. All positive controls responded appropriately except sodium azide with TA100 and TA1535 in the independent repeat study without S9-mix. The report indicated that sodium azide was either defective or prepared incorrectly.
Result:	The test material was non mutagenic under the conditions of

the test.

9.3.2 Chromosomal Aberration Assay

The notifier applied for variation for chromosomal aberration study.

9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Mouse

The notifier applied for variation for the study of micronucleus assay.

9.4 Overall Assessment of Toxicological Data

The notified polymer was of very low acute toxicity in rats. It was a slight skin and eye irritant in rabbits. The notified polymer was not mutagenic in bacterial strains tested with or without S9- mix.

The notifier sought variation for scheduled data requirements for the following toxicological endpoints: acute dermal toxicity, skin sensitisation and repeat dose toxicity on the basis of the low acute oral toxicity of the notified polymer, its high molecular weight resulting in low bioavailability and low potential for bioaccumulation. A study was not provided to ascertain the potential for chromosomal damage given the expected low bioavailability and the negative point mutation assay. No analogue data were provided.

Considering the low residual monomer content, percentage of low molecular weight species (<500) and proposed import volume of up to 5 tonnes per annum, the request for variation is accepted. However, should the import volume exceed 5 tonnes per annum, additional toxicological studies will be required (see recommendations, secondary notification).

Based on the available data, the notified polymer cannot be classified against the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Full test reports on the ecotoxicity studies for the notified polymer were provided by the notifier.

Test	*Species*	*Results*
48 h Acute Toxicity	Golden orphs *Leuciscus idus*	No mortality observed
16 h Bacterial Inhibition	Bacteria *Pseudomonas putida*	No significant inhibitory effects observed

The ecotoxicity tests were performed on the Water Soluble Fraction (WSF) of the notified polymer. The WSF was prepared by adding an amount of the notified polymer to water to give the required loading rate and the resulting solution was then stirred overnight. The mixture was filtered to remove undissolved test material.

The test on fish (BioChem GmdH, 1996b) was performed using a static methodology. Observations were performed after 48 h (less than the OECD standard of 96 h) and the test conducted at a temperature of 20 °C. The tests were conducted using a water soluble fraction (WSF) of the test substance made up at a nominal concentration of 150 mg/L. Analysis of the control and WSF at the beginning of the test showed measured concentrations of DOC of 1.12 and 2.913 mg/L, respectively. The results of the definitive study showed that no mortalities were observed at a nominal concentration of 150 mg/L filtered WSF.

The 16 h cell multiplication inhibition test with *Pseudomonas* (BioChem GmdH, 1996c) was also performed under static conditions and at a temperature of 21 °C. The tests were conducted using a water soluble fraction (WSF) of the test substance made up at nominal concentrations of 540 mg/L. Analysis of the WSF at the beginning of the test showed measured DOC concentration of 1.9 mg/L, which after addition of the culture medium was reduced to 1.5 mg/L. After 16 h, the mean value of cell multiplication inhibition was 5.3%.

No studies of toxicity to daphnia or algae were provided in this submission. The notifier argued that according to the USEPA TSCA New Chemicals Program (NCP) Chemical Categories (USEPA, 1988) high molecular weight aliphatic amines were equally toxic to all aquatic organisms. From an environmental stand point, the notified polymer is better classified as a polycationic polymer. According to USEPA (1988), algae are up to six times more sensitive to polycationic polymers than are fish and daphnia. However, little aquatic exposure is anticipated from the purposed use in solvent based paints.

The ecotoxicity data indicates the notified polymer is not toxic to fish and does not significantly inhibit the cell multiplication of *Pseudomonas* up to the limit of its water solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified polymer will be combined with other paint components to form a very high molecular weight and stable paint film. Therefore, once incorporated into the paint formulation, the notified polymer is expected to be immobile and pose little risk to the environment. As the coating degrades over time, any fragments, chips and flakes of the lacquer will be of little concern as they are expected to be inert. The metal panels and car bodies coated with the polymer are likely to be either recycled for steel reclamation or be placed into landfill at the end of their useful life. When recycled the polymer would be destroyed in furnaces and converted to water vapour and oxides of carbon

The notified polymer in waste from spills, equipment cleaning and drum recycling will be collected by licensed waste disposal contractors and treated by a distillation process whereby the solvent is reclaimed and the remaining solid containing the notified polymer will be disposed of in landfill. The notified polymer in overspray will also be disposed of in landfill. The notifier indicates that incineration of waste may also occur. Approximately 3.7 tonnes of the notified polymer will be released to the environment per annum.

The notified polymer is not water soluble and therefore will not be mobile in either the terrestrial or aquatic compartments. As a consequence of its cationic nature, the notified polymer is expected to eventually associate with the soil matrix and sediments. The notified polymer is not expected to cross biological membranes due to its high molecular weight and

low water solubility and is therefore not expected to bioaccumulate (Connell, 1990). Furthermore, ecotoxicity data indicates the notified polymer is not toxic to fish and does not significantly inhibit the cell multiplication of *Pseudomonas* up to the limit of its water solubility.

The notified polymer is not likely to present a hazard to the environment when it is stored, transported and used in the proposed manner.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard assessment

Anti-Terra-204 WS was of very low acute toxicity in rats. It was a slight skin and eye irritant in rabbits. The notified polymer was not mutagenic in bacterial strains tested with or without S9- mix. Based on the available data, the notified polymer cannot be classified against the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b).

The imported polymer solution, Anti-Terra-204, containing approximately 50% notified polymer is a hazardous substance due to the concentration of petroleum solvent present (NOHSC, 1999a). The risk phrases R38 'Irritating to skin', R45, 'May cause cancer' (if benzene content is >0.1%) and R65 'Harmful: May cause lung damage if swallowed' apply. The polymer solution is also classed as a Class 3 dangerous good. The MSDS for the polymer solution Anti-Terra-204 lists a number of potential health effects, namely nausea, vomiting, abdominal pain, headaches, dizziness, along with skin, eye, gastrointestinal and respiratory irritation. These relate to the solvents rather than the notified polymer.

Occupational Health and Safety

There is little potential for significant occupational exposure to the notified polymer in the transport and storage of the paint components containing this polymer. There will be exposure during the local formulation of the colorant dispersion, paint and paste products, and in the use and disposal of these products.

During the colorant dispersion and paint products manufacturing processes, the main exposure route for the notified polymer will be dermal. The polymer solution and the paint/paste products will be viscous, and ready formation of aerosols is not expected. The polymer is not expected to be hazardous by dermal exposure as the high molecular weight will preclude absorption through the skin. Protective measures used to prevent exposure to the hazardous solvents should provide sufficient protection against the notified polymer.

The final paint mix, including the pre-prepared paint containing the notified polymer, could contain a wide variety of additional ingredients once fully mixed. This is likely to introduce human health hazards because, apart from a range of potentially toxic solvents, there may be components containing resins with pendant isocyanate groups. The spraying procedure also produces a dense aerosol of paint particles which would adversely affect human health even in the absence of additional hazardous components. It is also probable that professionals involved in the spray painting industry will use a number of different paint formulations.

For these reasons, the notified polymer must be assessed for the contribution it makes to the hazards associated with use of the spray paints. The presence of many potential and actual hazardous substances in the formulations requires the use of stringent engineering controls,

such as a correctly constructed and maintained spray booth, and of a high level of personal protective equipment, such as impermeable overalls and gloves and a full face shield and respirator. The use of the paint containing the notified polymer should be in accordance with the NOHSC *National Guidance material for Spray painting* (NOHSC, 1999c). The level of protection from exposure afforded by the standard protective measures will provide adequate protection from the notified polymer, which is likely to be less intrinsically toxic than most of the solvents, pigments and other paint resins.

The professional painters will wear overalls during roller/brush application. Due to the low hazard profile of the notified polymer and the low concentration of the notified polymer in the final painting products, the health risk for these professional painters use the paint products containing the notified polymer with roller/brush application is expected to be low.

Once the applied final paint mix has hardened, the polymer will not be separately available for exposure or absorption.

The paint components containing the notified polymer are flammable due to their solvent content. Precautions must be taken to avoid sources of ignition, e.g. use of earthing leads. Operators should wear antistatic overalls and footwear.

Similar considerations apply in the disposal of the polymer. The wastes containing the notified polymer may be hazardous substances on the basis of the solvent and other resin content, and the precautions used on the basis of these additional materials should be adequate for protection from the notified polymer. In addition, much of the polymer will be crosslinked, hardened and immobilised by the time of disposal.

Public Health

Members of the public may be exposed to the notified polymer following transport accidents or following its contamination of the environment. However the likelihood of transport accidents involving the notified polymer or of the environmental dispersion of the notified polymer is low. DIY painters may come in contact with low concentrations of the notified polymer. However, the frequency of exposure is expected to be low. Any contact that does occur will most likely be dermal. It has a high molecular weight and thus a low capacity to penetrate biological membranes. It has a low acute toxicity and it does not irritate the skin. After the application of a coating containing the notified polymer, it is heat cured on the finished product. The notified polymer is then present in the coating as an inert and inaccessible component. It is considered that the notified polymer will not pose a significant risk to public health when used as intended.

13. RECOMMENDATIONS

Control Measures

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to Anti-Terra 204 containing the notified polymer:
  -enclosure of mixing tanks during formulation to prevent exposure to aerosols

-local exhaust ventilation during transfer of notified polymer from drum to mixing tank.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of Anti-Terra 204 containing the notified polymer:

  - avoid splashing and generation of aerosols during transfer of Anti-Terra 204 to mixing tank

  -for use of products containing the notified polymer, minimise the use of spray during cleaning operations

  -workers using spray products containing the notified polymer be instructed in their proper handling and use, including information about the additional risks posed by spray application and heat

  -application of spray containing the notified polymer should be in accordance with the NOHSC *National Guidance Material for Spray Painting.*

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to Anti-Terra 204 containing the notified polymer:
  -gloves
  -overalls
  -eye protection
  -respirator (during spray painting).

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Employers should ensure that NOHSC Exposure Standards for all of the components of the final paint mix are not exceeded in the workplace.

- 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.

13.1 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.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the polymer solution and formulated product were provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

These MSDS were provided by the applicants as part of the notification statement. They are reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicants.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, the director must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise, and secondary notification of the notified chemical may be required. No other specific conditions are prescribed.

16. REFERENCES

BioChem GmbH (1996a): Biodegradability Modified OECD Screening Test according to OECD-Guideline No.301 E BYK-LP N6649, Karlsruhe, Germany, (unpublished report submitted by BYK-Chemie GmdH).

BioChem GmbH (1996b): Determination of the Effect of Substances in Water on Fish according to DIN Guideline 38412, part 15, Karlsruhe, Germany, (unpublished report submitted by BYK-Chemie GmdH).

BioChem GmbH (1996c): Determination of the Inhibitory Effect of Water Constituents on Bacteria Pseudomonas Cell Multiplication Test according to DIN Guideline 38412, L 8, Karlsruhe, Germany, (unpublished report submitted by BYK-Chemie GmdH).

Connell D. W. (1990) General characteristics of organic compounds which exhibit bioaccumulation. In Connell D. W., (Ed) Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, USA.

National Occupational Health and Safety Commission (1994) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999a) List of Designated Hazardous Substances [NOHSC:10005(1999)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999b) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999c) national Guidance Material for Spraying Painting, Australian Government Publishing Service, Canberra.

Pharmatox GmbH (1985a) Acute toxicological study of Anti Terra 204 WS after oral application on the rat, Pharmatox GmbH, Germany.

Pharmatox GmbH (1985b) Irritation effects of Anti Terra 204 WS on rabbit skin as a 50 p.c. emulsion, Pharmatox GmbH, Germany.

Pharmatox GmbH (1985c) Irritation effects of compound Anti Terra 204 WS (50 p.c. in Tylose) on rabbit eye, Pharmatox GmbH, Germany.

Springborn Laboratories (1999a) Study No.: 13502.0298.6127.740 Anti-Terra 204 WS Determination of Vapour Pressure, Wareham, USA, (unpublished report submitted by BYK-Chemie USA).

Springborn Laboratories (1999b) Study No.: 13502.0298.6126.700 Anti-Terra 204 WS Determination of Water Solubility, Wareham, USA, (unpublished report submitted by BYK-Chemie USA).

Springborn Laboratories (1999c) Study No.: 13502.6149 Anti-Terra 204 WS Determination of *n*-Octanol Solubility, Wareham, USA, (unpublished report submitted by BYK-Chemie USA).

Springborn Laboratories (1999d) Anti-Terra 204WS, Determination of *Salmonella* direct plate incorporation mutagenicity assay (Ames test), No. 13502.1098.6147.777, Springborn Laboratories Inc, USA.

USEPA (1988) TSCA New Chemicals Program (NCP) Chemical Categories http://www.epa.gov/oppt/newchems/chemcat.pdf

Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

Draize, J. H., Woodward, G., Calvery, H. O. (1944) Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol. Exp. Ther. 82 : 377-390.

Draize J. H. (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49 : 2-56.