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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Anti-Terra-204 WS

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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

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FULL PUBLIC REPORT

Anti-Terra-204 WS

1. APPLICANT

Original Holder of Assessment Certificate (First Applicant)

An Assessment Certificate for the notified chemical known by the name Anti-Terra-204 WS was granted to 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).

The Assessment Report for Anti-Terra-204 WS is identified by the sequence number NA/922.

Second Applicant

Since granting of the abovementioned Assessment Certificate, BASF Coatings Pty Ltd, 231-233 Newton Road WETHERILL PARK NSW 2164 has submitted a notification statement in support of their application for an extension of the original Assessment Certificate for Anti-Terra-204 WS. Nuplex Industries (Aust) Pty Ltd and Degussa Coating & Colorants Pty Ltd have agreed to this extension.

Information submitted by BASF Coatings Pty Ltd pertains to the introduction of the notified chemical for use as a component in solvent based paint used in the automotive industry. Introduction volumes will be less than 1000 kg per year imported as a component of the coating product.

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(s) Anti-Terra-204 WS

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: $956 \text{ kg/m}^3 \text{ at } 20^{\circ}\text{C}$

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: $> 100^{\circ}$ 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 20°C 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 °C. 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 °C, 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

Mode of Introduction of Notified Chemical (100%) Over Next 5 Years Imported.

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

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

Use

Solvent based paint used in the automotive industry..

Port of Entry Sydney

Identity of Manufacturer/Recipients

BASF Coatings Pty Ltd located at 231-233 Newton Road, Wetherill Park NSW 2164.

5.1.3 Transportation and Packaging

The notified polymer will be imported in 30 L, 15 L, 3.5 L, 1 L and 500 mL steel cans as an ingredient in different paint lines. From the dockside, the notified polymer will be offloaded and shipped by road transport to BASF Coatings warehouse at Wetherill Park, NSW.

6. OCCUPATIONAL EXPOSURE

Number and Category of Workers

Category of Worker	Number	Exposure Duration	Exposure Frequency
Notifiers Site			
Transport & Warehousing	10	1-2 hours	200 days/year
At Car manufactures			
Paint Application			
Unloading of paint and preparation of	1-2	1-2 hours	200 days/year
mixture			
Spray painting	20	8 hours/day	200 days/year
Cleaning equipment	10	2 hours/day	200 days/year
Aftermarket industry e.g. Crash car shop			
Unloading and preparation of mixture	1-2	1 hour	24 days/year
Spray painting	2	10-45 mins	200 days/year
Cleaning equipment	2	15 mins	200 days/year

Exposure Details

Given the nature of the processes involved in handling new products containing the notified polymer, it is estimated that the total number of workers potentially exposed to the new polymer will be high, but that the total time of exposure will be relatively low and the concentration of the notified polymer in finished paint will be low. The possibility of incidental contact with this chemical will be minimised by good industrial hygiene practices and proper protective equipment, essential for the protection against exposure to the solvent carriers and other ingredients contained in the new products.

The paints containing the notified polymer will be imported by sea as part of a mixed load of chemicals. It is anticipated that 1-2 deliveries will occur per month. It is expected that less than 10 workers would be involved in receiving the import at the dock, the transport of the materials to storage of BASF Coatings Pty Ltd warehouse and dispatch from the warehouse. The customers, (car manufactures and crash repair shops) located in metropolitan areas around Australia will receive the paint in its original packaging.

Car manufacturing Sites

At the car manufacturing workshops the operations are continuous and workers are dedicated to individual tasks. At each individual car manufacturing workshop, one or two workers are required to unload the paint containing the notified polymer, deliveries are estimated to occur once or twice per month. The same workers also assist in preparation of the mixture. A total of 20 workers will be involved in spray painting. The spray painters will open the steel can of the finished paint containing the notified polymer and may mix it with other additives prior to application. The mixture is then loaded into the spray equipment and applied to the car in a spray booth.

Once spraying in completed or the paint has been exhausted, the equipment is drained and cleaned using solvents and rags. Approximately 10 workers are involved in the cleaning of equipment. The rinsates and used rags are collected for disposal. Empty cans are drained onto absorbent material and the cans are disposed of to landfill. Spray booth filters will be removed by workers for disposal every 2-4 months.

Aftermarket industry - Crash car shop

At each individual crash shop, one person is required to unload the paint containing the notified polymer. Deliveries are estimated to occur once or twice per month.

One to two operators at each crash car workshop will be involved in using the new paints for spray panel repair. Preparation of the ready to spray mixture usually takes between 10-15 mins. Spraying time will vary from 10 minutes for a single panel repair to 45 minutes for a full vehicle spray. Given that the majority of a spray-painter's time is spent in the preparation of the surface, it is estimated that during any week, a spray-painter will have the potential to be exposed to the notified polymer for a maximum of five hours per week.

Small Car Repair workshops

In a well ventilated area the spray painter will spread newspaper sheets on the ground around the particular area to be painted. The newspaper sheets will collect any waste paint and overspray from spray painting. Once spraying is completed or the paint has been exhausted, the equipment is drained and cleaned using solvents and rags. Empty cans are drained onto absorbent material and the cans are collected by licensed contractor. The newspaper sheets with the paint material are disposed of in a bin which is also collected by a licensed contractor.

It is estimated that there will be approximately 1000 spray-painters around Australia who will use the new paints containing the notified polymer on a regular basis. Each

painter will on average undertake approximately 150 jobs per year at an average application time of 15 minutes

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

Release of Chemical at Site

Release at the notifier's warehouse may result due to accidental spills. It is estimated that a maximum of 5% of the notified chemical (~1.2 kg per year of notified polymer) would be lost during spillage. Spills are contained and soaked up with inert absorbent material (sand, soil or vermiculite) and placed in a sealable container for appropriate disposal. Waste material is disposed of in accordance with local, state or national EPA regulations.

Release of Chemical from Use

Release of the notified polymer to the environment as a result of its use in car manufacturing industries and crash repair shops around Australia is expected to be minimal, unless an accidental spillage occurs.

Accidental spills

If accidental spillage occurs during normal operating procedures, it will be contained and soaked up with inert absorbent material (sand) and placed in a sealable container for disposal. Waste material is disposed of in accordance with Local, State or National EPA regulations.

Residues in empty containers

The finished paint products will be packaged in 30 L, 15 L, 3.5 L, 1 L and 500 mL steel cans. The steel cans will be disposed off to landfill. The residues in the containers are expected to account for up to 5 % of the import volume (~2.2 kg per year of the notified polymer). The table below provides an estimate of the residue of the notified substance in the empty containers and the disposal method in place.

Type and size of container	Residue in empty container	Proportion of import volume of notified	Amount disposed per	Amount disposed per
	(%)	chemical per container (g)	year (kg)	year (kg)

500 ml steel can	5	0.18	0.5	Landfill
1 L steel can	3	0.21	0.9	Landfill
3.5 L steel can	2	0.50	0.6	Landfill
15 L steel can	1	1.05	0.15	Landfill
30 L steel can	0.5	1.05	0.075	Landfill

Over<u>spray</u>

A loss of 30% of the ready-for use material is achieved by the use of HVLP spray guns and slightly higher loss with the more outdated high pressure guns. The engineering controls for over-spray are typically spray booth filters and water scrubbers. The spray booth filters are usually renewed every 2-4 months. The filters are disposed of according to Local, State, National EPA regulations as are the scrubber waters. This can be done privately or professionally depending on the vehicle repair shop management.

Based on 30% (worst case) over-spray losses during application procedures, a level of notified polymer in paint mixtures and an annual import volume of 100 kg, it is expected that approximately 0.21 kg of notified polymer per annum would be lost via overspray.

Smaller workshops may not have spray booths. Overspray is collected on newspaper sheets which are disposed off to landfill. Based on 2% losses from spray painting, it is expected that approximately 0.014 kg of the notified polymer per annum would be lost in this manner

Cleaning of equipment

Based on 5% losses from cleaning of equipment after application procedures, a level of notified polymer in paint mixtures and an annual import volume of 100 kg, it is expected that approximately 0.035 kg of notified polymer per annum would be lost via cleaning of equipment.

8.2 Fate

Disposal

Paint containers containing residues of the polymer will be disposed of either professionally or privately depending on operations of the Spray shops.

If incidental spillage occurs during normal operating procedures, it will be contained and soaked up with inert absorbent material (sand, soil or vermiculite) and placed in a sealable container for appropriate disposal. Waste material is disposed of in accordance with local, state or national EPA regulations.

Any overspray of the new material that does occur would be trapped in the spray booth and removed to an approved landfill in accordance with local, state or national EPA regulations.

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	1	,	2	2	3	3	4	1	5	5
treatment (days)	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.

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)

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^a see Attachment 1 for Draize scales

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 the study.	for cornea (opac	ity and area) were zero for all animals during
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,
2	1	0	1	1	0	1	chemosis and discharge) were zero for all animals from 4 hour to day 7.
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	No mortality observed
	Leuciscus idus	
16 h Bacterial Inhibition	Bacteria	No significant inhibitory
	Pseudomonas putida	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 Diffuse beefy red	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and	2 mod.
		Swelling with lids half- closed	3 mod.	adjacent hairs Discharge with	3 severe
	3 severe	Swelling with lids half- closed to completely closed	4 severe	moistening of lids and hairs and considerable area around eye	

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.