File No: NA/537

January 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Pigment Additive AC

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Pigment Additive AC

1. APPLICANT

Hoechst Australia Limited of 606 St Kilda Road MELBOURNE VIC 3004 and Croda Herberts Pty Ltd of 15-23 Melbourne Road RIVERSTONE NSW 2765 have jointly submitted a standard notification statement in support of their application for an assessment certificate for Pigment Additive AC

2. IDENTITY OF THE CHEMICAL

Although Pigment Additive AC is considered to be hazardous based on its skin sensitising potential, the imported pigment product in which it is a component is not classified as hazardous. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, and details of exact import volume and customers have been exempted from publication in the Full Public Report and the Summary Report.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	red odourless powder
Melting Point:	> 320°C
Specific Gravity:	1.39
Vapour Pressure:	< 10^{-8} kPa at 20°C
Water Solubility:	0.6 mg.L^{-1} at 20°C
Fat Solubility:	< 0.01 g per 100 g fat at 37 ºC
Partition Co-efficient (n-octanol/water):	log P_{ow} = 3.28
Hydrolysis as a Function of pH:	not determined (see comments below)
Adsorption/Desorption:	not determined (see comments below)

Dissociation Constant:	not determined (see comments below)
Flash Point:	not determined
Flammability Limits:	not determined
Autoignition Temperature:	350°C
Explosive Properties:	not explosive
Reactivity/Stability:	the notifiers state that an exothermic reaction with combustable material is not expected, based on the structual formula

Comments on Physico-Chemical Properties

The reported water solubility result of less than 0.6 $mg.L^{-1}$ was determined by gravimetric determination. However, the notifier has performed an additional spectrometric procedure which determined the water solubility to be less than 20 $\mu g.L^{-1}$ (i.e. less than the detection limit). A study report for the latter was not supplied.

The notifier claims that due to the notified chemical's very low water solubility, hydrolysis testing was not possible according to EEC Guideline 84/449 C10. Mixing the chemical with a water miscible organic solvent (maximum 1% permitted) did not result in any visible increase in solubility. Hydrolysis of the notified chemical in the environmental pH range will be precluded by its very low solubility and any hydrolysis of the sulfonamide functionalities is expected to be extremely slow.

Since the notified chemical has a very low water solubility, the partition coefficient was calculated using CLOGP 3.4 estimation software according to Guideline 84/449/EEC A8. No further information on these calculations could be obtained from the notifier. The notified chemical's solubility in 1-octanol is claimed to be 0.45 $mg.L^{-1}$.

The notified chemical will not be imported into Australia as the technical material, but as a component of a pigment. The notifier claims that due to the affinity of the chemical to this pigment and its low water solubility, the additive is not expected to move between the water and soil compartments of the environment. Considering its very low solubility in water, it is expected that the notified chemical will be immobile, adsorbing to, or being associated with, soil and sediment.

Due to the very low water solubility, the notifier claims that it is not feasible to determine a dissociation constant. The presence of two tertiary amine functionalities is expected to impart typical basicity to the notified chemical (pK_a ~ 10) {J B Henrickson D J Cram and G S Hammond, 1970 #103}, with solubility increasing in acidic solutions.

The substance also has low fat solubility.

4. PURITY OF THE CHEMICAL

Degree of Purity: 90-100%

Non-hazardous Impurities (> 1% by weight):

Chemical Name	*Weight %*
water	2.2
organic impurities (unknown)	<2.8

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will be imported from Germany as a component of the pigment Hostaperm. It will be imported into Australia in 25 kg multi-walled paper bags for use in automotive paint products, as a component of finished paint products and as a component of finished toner products in sealed cartridges.

The notified chemical will be used as an additive to improve the rheological (deformation and flow) characteristics and colouristic properties of pigments. The additive will comprise less than 10% of the pigment which will be used in the production of paints for automotive purposes and tinter products for colour toners.

Production of automotive paints will involve the mixing of imported pigment containing the notified chemical with other materials such as resins, solvents and paint additives, in a mixing vessel. Pigments will be included in paint products at levels up to 15% of the product, The finished paint products will be packaged in 4 L containers and used only by professionals in the spray painting of new and used cars.

No formulation of toner products will occur in Australia. Toner products will be imported in sealed cartridges, which are designed for direct insertion into photocopy machines and laser printers to replace empty cartridges. Toner products will contain between 5 to 10% pigment.

6. OCCUPATIONAL EXPOSURE

Workers may be exposed to the notified chemical to varying degrees in pre-formulated paints, as an ingredient in raw pigment, or toner. In the case of the latter, the toner will arrive in Australia in sealed cartridges. Occupational exposure will only occur during handling and transport through accidental spillage. Office workers may also experience exposure through this means and also as a consequence of replacement of toner cartridges. However, normal exposure is expected to be minimal. Photocopier maintenence personnel may also be exposed to small quantities of the notified chemical.

Exposure of workers to the notified chemical is expected to be greatest during paint

formulation. Some 20 stores/warehouse personnel and 27 production/filling personnel are potentially exposed to the greatest quantities. Stores personnel handle 25 kg multi-walled paper bags of the pigment containing the notified chemical, for an estimated one hour per day on 8 days per year. Exposure is only likely to occur through accidental spillage. A greater risk of dermal, eye and inhalational exposure occurs with the production personnel involved in emptying bags of the pigment into mixing vessels.

Finally, worker exposure to the notified chemical can occur through exposure of workers to paint formulations containing the notified chemical. Filling personnel using mechanical filling equipment are likely to have a maximum exposure of 20 working days per year at approximately 2 hours per working day. Quality control/research and development personnel may also be exposed to small quantities of finished product containing the notified chemical at an estimated exposure of 1 hour per day on 12 days per year. Use of the final products may expose training and demonstration personnel as well as customers to small quantities of the notified chemical.

7. PUBLIC EXPOSURE

Products containing the notified chemical will be widely used in office environments and in automative spray painting applications. Toner cartridges for photocopiers and laser printers are sealed and the concentration of the notified chemical in these products is low. Although considerable contact with printed papers will occur, exposure to the notified chemical bound into the printing will be minimal. In the case of spray painting operations, the spray booths used to protect operators will also reduce dispersal of spray paints to the surroundings and public exposure from this source is expected to be negligible.

In the event of a transport accident, the notified chemical at low concentrations in paint and toner products is not expected to pose a significant hazard. As the notified chemical has low water solubility (0.6 $mg.L^{-1}$) it is unlikely to enter the water supply following a spill, and hence potential for public exposure via this means is negligible.

8. ENVIRONMENTAL EXPOSURE

Release

Paint Manufacture

Production of paints is expected to occur at four sites. Mixing vessels and mills are washed with rinsing solutions re-incorporated into the manufacturing process. Based on previous experience, the notifier claims that approximately 3% of the formulation may occur as residue in equipment. Equipment is cleaned with wash solvent which is sent to a solvent recycler for recovery. Solid residue from processing is sent to an approved waste disposal site.

Major spills during paint manufacture will be collected by the drainage system which leads to a storage pit to prevent entry to the sewage system or waterways. Residue from the pit, as well as minor spills taken up with sand or other inert materials, are removed by waste disposal contractors and sent to an approved waste disposal site.

Dry pigment dust (notified chemical) is removed from the atmosphere by an extraction system and collected in a filter. The filters are removed by contractors and eventually disposed of to an approved waste disposal site. Residues in packaging are estimated at less than 1%. Empty bags will also be collected for disposal by contractors.

Paint Use

The finished products containing the notified chemical will only be available to automotive and industrial trade customers. The majority of finished product will become a dry paint film on the vehicle being painted.

The notifier recommends that the application of paint products containing the additive pigment (notified chemical) be restricted to spray booths with exhaust ventilation. It is claimed that during application, overspray losses can be as much as 30% of the material sprayed. It is noted that up to 70% of the paint may be lost through overspray and 'bounce-back' {Randall, 1992 #107; EPA (WA Environmental Protection Authority), 1992 #104}. However, release of the paint will be contained within spray booths. Overspray will be captured and collected through the spray booths' filtering system (dry booth) or water traps and coagulated (wet booth). The contaminated filters or contaminants from the water trap are disposed of according to waste disposal regulations of the relevant local government authority, and most likely landfilled.

Cleaning of the spray gun and mixing equipment will generate waste. It is assumed that these will be collected and, based on previous similar submissions, estimates these wastes to be approximately 10 to 20%. Liquid wastes are normally collected by licensed waste disposal contractors. The liquid is distilled off, leaving the final solids to be sent to trade-waste landfill.

Residues of paint remaining in cans are claimed by the notifier to be less than 1%. These residues are likely to dry within the can. Empty cans may be recycled. However, most containers may still be disposed of to industrial waste sites.

Toner Products

The notified chemical, as a component of a pre-formulated toner, will be imported in small, sealed cartridges. Seal tapes are only removed prior to the insertion into the photocopier or printer. Under normal use (i.e. photocopying and printing) the toner is transferred onto a sheet of paper where it is firmly fixed to the surface by heat. Thus the chemical will be fixed into the cured toner and release to the environment will be negligible. Waste paper containing the toner (and thus the notified chemical) will eventually be sent to landfill, recycled or incinerated.

Release of the notified chemical will also occur through the disposal of cartridges containing residues of the toner. The expected residual volume of the notified chemical would only be approximately 0.1 g. The spent toner cartridges will be disposed of as normal office waste, which in turn will go to landfill.

Environmental release during transport due to accidental spillage will be limited due to the toner being supplied in small plastic cartridges.

Fate

When Used in Paint Products

Isocyanate hardener is added immediately before application. The majority of the notified chemical is not expected to be released to the environment until it has been fully cured into a solid polymer matrix. The coating containing the crosslinked polymer, and thus notified chemical, will share the fate of the automotive panels to which it is applied. Any chips or flakes of the cured paint that occur (due to stone chips, accidents, wear and tear, etc) will be inert, diffuse and form part of the sediments.

When the polymer is disposed of in waste spray, the chemical should remain bound (encapsulated) within the matrix of unpolymerised paint residues/wastes should they be disposed of to landfill. No hydrolysis, movement, leaching, biodegradation or bioaccumulation of the chemical in the polymer is expected.

When Used in Toner Products

The fate of the notified chemical will be similar to that of the toner once it has been cured. Unless incinerated, it is likely to be disposed of by landfill, either bound to waste paper or sludge (from the paper recycling process). As such, the toner will be immobile. As the notified chemical is not expected to leach from the cured toner, no leaching of the notified chemical from landfill is expected.

When uncured toner is disposed of to landfill the very low water solubility and expected adsorption to soil and sediment should see the notified chemical become immobile. Leaching within landfill is not expected.

In General

Incineration of the notified chemical in the presence of excess air is expected to produce water and oxides of carbon, sulfur and nitrogen.

Biodegradability testing according to the modified Sturm test (OECD Test Guideline 301B) [OECD, 1989] indicated that the notified chemical is not readily biodegradable. CO_2 formation reached only 30% of theoretical maximum within the stipulated period of 30 days. However, the guideline notes that because of the stringency of the test, failure to meet these criteria does not mean that the test substance will not be biodegradable in the natural environment [OECD, 1989]. Therefore, the result suggests that the chemical is potentially degradable or would be partially degradable in the natural environment.

Bioaccumulation of the notified chemical is not expected due to its low water solubility, high molecular weight and low fat solubility {Anliker, 1988 #2; Connell, 1989 #3}

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Pigment Additive AC

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 000 $mg.kg^{-1}$	{T Hofmann and R Jung, 1989 #108}
acute dermal toxicity	rat	LD_{50} > 2 000 $mg.kg^{-1}$	{T Hofmann and R Jung, 1989 #109}
skin irritation	rabbit	non-irritant	{Kreiling and Jung, 1989 #110}
eye irritation	rabbit	mild eye irritant	{Kreiling and Jung, 1989 #111}
skin sensitisation	guinea pig	moderate skin sensitiser*	{T Hofmann and R Jung, 1989 #112}

* Skin sensitisation data for imported pigment product (challenge concentration of notified chemical at 0.025%) indicates that the skin sensitisation potential of the notified chemical is ameliorated See Section 9.1.6b.

9.1.1 Acute Oral Toxicity {T Hofmann and R Jung, 1989 #108}

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage; vehicle was 2% aqueous starch solution
Clinical observations:	faecal discolouration was noted in all animals one day after administration of the test material; no other clinical signs were noted
Mortality:	none
Morphological findings:	none
Test method:	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of low acute oral toxicity in a limit test in rats

9.1.2 Dermal Toxicity {T Hofmann and R Jung, 1989 #109}

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	occluded dermal application of 2 000 mg/kg of the notified chemical wetted with polyethylene glycol 400; bandage removed after 24 hours and treated area washed with leukwarm water
Clinical observations:	body weight gain in female animals was slightly decreased; no other clinical signs were noted
Mortality:	none
Morphological findings:	one female had a spleen with an uneven surface

Test method:	similar to OECD guidelines {Organisation for Economic Co-operation and Development, 1995-1996 #15}
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of low acute dermal toxicity in a dermal limit test in rats

9.1.3 Inhalation Toxicity

No data was provided by the notifiers.

9.1.4 Skin Irritation {Kreiling and Jung, 1989 #110}

Species/strain:	rabbit/New Zealand White
Number:	3
Observation period:	3 days
Method of administration:	semi-occlusive application of 500 mg of the notified chemical in 0.35 mL polyethylene glycol to the intact, shorn skin in the dorsal region of the trunk; 4 hour exposure
Draize Scores	during the entire test period the animals showed no signs of irritation
Test method:	similar to OECD guidelines
Result:	the notified chemical was not a skin irritant in rabbits

9.1.5 Eye Irritation {Kreiling and Jung, 1989 #111}

Species/strain:	rabbit/New Zealand White
Number:	3
Observation period:	7 days
Method of administration:	100 mg of the notified chemical was applied to the conjunctival sac of the left eye of each animal; untreated eye served as the control

Draize scores {Draize, 1959 #4}) of unirrigated eyes:

Time after instillation

Animal	***1 hour***		***1 day***		***2 days***		***3 days***		***7 days***	
Conjunctiva	***r[c]***	***c[d]***	***r[c]***	***c[d]***	***r[c]***	***c[d]***	***r[c]***	***c[d]***	***r[c]***	***c[d]***
1	1	2	3	2	2	0	2	0	0	0
2	2	1	2	3	1	1	1	0	0	0
3	2	2	3	2	1	0	1	0	0	0

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

Comments: no corneal or iridial effects were observed in any animal; the notified chemical cause conjuntival reddening and chemosis, with the chemosis disappearing by day 3, and the redness by day 7

Test method: similar to OECD guidelines

Result: the notified chemical was a mild irritant to the eyes of rabbits

9.1.6a Skin Sensitisation Data for Pigment Additive AC {T Hofmann and R Jung, 1989 #112}

Species/strain: guinea pig/Pirbright White

Number of animals: 10 test and 5 control animals

Induction procedure: day 1 - each animal was injected intradermally twice using the following 0.2 mL preparations:

50% FCA solution
1% notified chemical in viscous paraffin DAB
1% notified chemical in 50% FCA

day 8 - 0.5 mL of the notified chemical (2.5%) in viscous paraffin DAB was applied to the injection site using an occlusive bandage for a period of 48 hours

Challenge procedure: day 22 - 0.5 mL of the notified chemical (0.25%) in viscous paraffin DAB was applied to the shaved flank site using an occlusive bandage for a period of 24 hours

day 29 - repeat of procedure carried out on day 22 with a 0.025% concentration of the notified chemical

Challenge outcome:

Challenge concentration	Test animals		Control animals	
	48 hours*	72 hours*	48 hours	72 hours
0.25%	6/10**	6/10	0/5	3/5
0.025%	6/10	4/10	0/5	0/5

* time after patch removal
** number of animals exhibiting positive response

Test method: similar to OECD guidelines

Result: the notified chemical was a moderate sensitiser to the skin of guinea pigs

9.1.6b Skin Sensitisation Data for the Pigment containing the Pigment Additive AC {Bury, 1995 #128}

Species/strain: guinea pig/Pirbright White

Number of animals: 10 test and 5 control animals

Induction procedure: day 1 intradermal induction - each animal was injected intradermally twice using the following 0.2 mL preparations:

1) 50% FCA solution
2) 1%pigment in semi-liquid paraffin
3) 1% pigment in 50% FCA

day 8 dermal induction - 0.5 g (25%) of the pigment containing in petrolatum was applied near the injection site using an occlusive bandage for a period of 48 hours

Challenge procedure: day 22 - 0.5 g of the pigment (5%) in viscous paraffin was applied to the shaved flank site using an occlusive bandage for a period of 24 hours

Challenge outcome:

Challenge concentration	Test animals		Control animals	
	48 hours*	72 hours*	48 hours	72 hours
0.25%	0/10**	0/10	0/5	0/5
0.025%	0/10	0/10	0/5	0/5

* time after patch removal
** number of animals exhibiting positive response

Test method:	similar to OECD guidelines
Result:	the pigment (5%) containing the notified chemical (at < 1%) was not a sensitiser to the skin of guinea pigs

9.2 Repeated Dose Toxicity {T Hofmann R Jung D Mayer and K Langer, 1989 #113}

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex
Method of administration:	oral gavage in 2% starch mucilage vehicle
Dose/Study duration::	0, 62.5, 250, 1 000 $mg.kg^{-1}.day^{-1}$/28 days
Clinical observations:	none
Clinical chemistry/Haematology	no treatment-related findings
Histopathology:	no treatment-related findings
Test method:	similar to OECD guidelines
Result:	the notified chemical was not toxic to rats in a repeat-dose test

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay {Muller, 1989 #114}

Strains:	TA 98, TA 100, TA 1535, TA 1537 and TA 1538
Concentration range:	4 - 5 000 μg per plate with and without metabolic activation
Test method:	similar to OECD guidelines
Comments:	visible precipitation commenced at doses of 500 μg per plate in all tests; no bacterial lawns were detected at 5 000 μg per plate
Result:	the notified chemical was not mutagenic to salmonella with or without metabolic activation

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse {Muller, 1989 #129}

Species/strain:	mouse/NMRI
Number and sex of animals:	5/sex (5 groups)
Doses:	0 (control), 50 and 5 000 $mg.kg^{-1}$
Method of administration:	dose given orally by gavage in a sesame oil vehicle
Test method:	similar to OECD guidelines
Result:	the notified chemical was considered non-clastogenic in the mouse micronucleus test at the dose and time intervals evaluated

9.4 Overall Assessment of Toxicological Data

The notified chemical is of low acute oral and dermal toxicity in rats with the LD_{50} in both cases exceeding 2 000 $mg.kg^{-1}$. Repeat dose oral toxicity studies with the rat showed that the notified chemical was not toxic when administered daily over a 28 day period. Skin irritation studies showed that the notified chemical was not a skin irritant to rabbits, while eye irritation studies indicate that it is mildly irritating.

The notifier has supplied two sets of skin sensitisation data. One set for the notified chemical, and the other for the pigment containing the notified chemical. The latter being the form of the notified chemical to which workers are exposed. Pure notified chemical is not imported, nor isolated from the imported product. With these two sets of data
notifier has shown that the sensitisation potential of the notified chemical is ameliorated in the pigment formulation, presumably because the notified chemical is bound to the pigment..

Since, precipitation of the notified chemical started to occur at 500 μg per plate, the mutagenicity results are equivocal.

The notified chemical would be classified as hazardous according to the *Approved Criteria of the National Occupational Health and Safety Commission* on the basis of its skin sensitisation potential.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicological data is not required for chemicals with import volumes less than 1 tonne per year according to the Act. However, the notifier has supplied ecotoxicity test reports for the zebra barbel and water flea.

Test	Species	Results (Nominal [1])	Reference
96 h Acute Toxicity Static & Semi-static [2] OECD TG 203	Zebra barbel (*Brachydanio rerio*)	LC_{50} [3] = 100-220 mg.L^{-1} LC_0 = 50 mg.L^{-1}	{Nolken and Jung, 1989 #106}
48 h Acute Immobilisation Static [4] 84/449/EEC	Water flea (*Daphnia magna*)	48 hours EC_{50} = 200 mg.L^{-1}	{Noack, 1989 #105}

1. The analytically determined quantities of the recovered substance were well below the nominal concentration. No pattern could be discerned. Therefore, the concentration data was given with respect to the nominal concentrations.

2. Due to the low water solubility of the notified chemical, TWEEN 80 was used as a dispersing agent to improve its distribution in water. Static testing was done at 100 & 220 mg.L^{-1} and semi-static testing at 50 & 100 mg.L^{-1} (fish transferred every 24 hours into new test tanks); Maintaining 80% of the desired concentration of the test substance over the entire trial period was not possible in either trial.

3. The author claims that probit analysis was not possible due to the mortality rate found.

4. No carriers/dispersing agents were used. Test concentrations were 1.0, 1.8, 3.2, 5.8, 10, 18, 32, 58, 100, 180, 320, 580 & 1 000 mg.L^{-1}. Sedimentation in all batches was noticed after 24 hours.

Two acute fish toxicity trials (static and semi-static conditions) were undertaken. In trial 1 (static) there was a 90% mortality rate at 220 mg.L^{-1} with no mortalities at 100 mg.L^{-1}. In trial 2 (semi-static), there was a 30% mortality rate at 100 mg.L^{-1} with no mortalities at 50 mg.L^{-1}. Observations were limited in both trials as the test media were strongly coloured. However, changes in swimming behaviour, i.e. drooping tail, fright reaction increase, reduced activity, swimming near tank floor and compromised breathing, were noticed after 24 hours in all test concentrations of both trials. Dead fish were of a lighter colour and had substance sedimentation on the body surface.

The ecotoxicity data for the notified chemical indicates that the notified chemical is practically non-toxic to fish and water invertebrates up to the level of its solubility. Sediment/particles were noticed absorbed to daphnia cuticula.

No algal toxicity data were supplied. As the notified chemical strongly coloured the test media in the above two tests, deleterious effect on algal growth may be caused by the interception of light (shading effect). Growth inhibition, whether due to chemical or physical factors, is still of relevance. Based on experience with coloured substances, it is likely the notified chemical will be slightly to moderately toxic to algae. However, based on the proposed use for the notified chemical, algistatic effects are unlikely to occur as aquatic environmental exposure will be low and not continuous.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The main environmental exposure of the chemical arises from the landfill disposal of recovered dry waste paint from the application process. It is estimated that up to 390 kg per year of the chemical may be consigned to landfill at maximum projected import volumes (30% overspray in application, 10% wastage through cleaning and 1% residues in paint cans). However, such material will be cured or bound to soil,

and remain immobile in the environment. The environmental hazard from such disposal is expected to be low.

The main environmental hazard would arise through spillage in transport accidents, that may release quantities of the uncured chemical (in either the imported powder form (pigment or toner) or in liquid paint form) to drains and waterways. Ecotoxicity test results indicate that it is non-toxic to fish and invertebrates up to the limits of its solubility. The chemical (products) will be imported in small containers that should limit the size of any spill. Adequate control procedures are outlined in the Material Safety Data Sheet (MSDS).

The chemical is unlikely to present a hazard to the environment when it is incorporated into paints and/or applied to the panels of cars. Such painted panels will be consigned to landfill or recycled at the end of their useful life. The environmental hazard from such exposure of cured paint products is expected to be low.

When used in toners, the majority of notified chemical should not enter the environment until it is incorporated into a polymer matrix when the toner is heat-cured and fixed to paper. Disposal of waste paper containing the toner is normally through landfill, incineration or recycling. In landfill the toner can be expected to persist but remain fixed to the paper substrate and remain immobile. Incineration products of the notified chemical should not produce an environmental hazard. After the recycling process, the toner will either remain bound to the pulp, or become associated with sludge and landfilled. Environmental exposure and the overall environmental hazard should be low.

Spent cartridges containing residues of toner will be sent to landfill, which will see approximately 5 kg of the notified chemical sent to landfill at maximum import quantities. Due to the chemical's very low water solubility and expected immobility in soils, movement of the chemical from landfill is unlikely. In any case, any notified chemical leaching from landfills and entering the aquatic compartment is likely to be diffuse and at concentrations not likely to pose a significant environmental hazard.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Based on the skin sensitisation studies on the notified chemical, it would be classified as hazardous according to the *Approved Criteria*. As the concentration of the notified chemical in the pigment product is above the 1% cut-off level, the pigment product would theoretically be classified as hazardous as well. However, data supplied by the notifier shows that guinea pigs treated with the same concentration of the notified chemical in combination with the pigment is insufficent to induce a sensitisation response. In effect, the pigment in combination with the pigment additive ameliorates the sensitising properties of the latter. While the scientific argument adopted by the notifier is plausible at a challenge concentration of less than 1% of the notified chemical, it may not be appropriate to extrapolate the lack of risk to the 20-fold greater concentrations of the notified chemical to which workers may be exposed during handling of the pigment. Accordingly, workers

involved in the transport and storage of packets of pigment may be at risk should they be exposed to the chemical through accidental exposure. Greater risk of worker exposure (dermal and ocular) to the notified chemical is likely to occur during the re-weighing of the notified chemical and addition of the notified chemical to the paint mixing vessels. Workers in this phase of operations should wear gloves and overalls to prevent exposure of the skin to the notified chemical, however such work practices should be used by all workers handling formulations containing the notified chemical. Upon blending of the pigment with the other paint ingredients, the risk posed to workers (eg filling personnel, training and demonstration personnel) is diminished since the concentration of the notified chemical in the finished product is less than 1%

The risk posed to workers exposed to the notified chemical as a component of photocopier toners is low because the concentration of the notified chemical is very low and the toner is contained within sealed cartridges.

13. RECOMMENDATIONS

To minimise occupational exposure to Pigment Additive AC the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 {Standards Australia, 1994 #21} to comply with Australian/New Zealand Standard (AS/NZS) 1337 {Standards Australia/Standards New Zealand, 1992 #23};
- Industrial clothing should conform to the specifications detailed in AS 2919 {Standards Australia, 1987 #18};
- Impermeable gloves or mittens should conform to AS 2161 {Standards Australia, 1978 #17};
- All occupational footwear should conform to AS/NZS 2210 {Standards Australia/Standards New Zealand, 1994 #24};
- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety*

Data Sheets {National Occupational Health and Safety Commission, 1994 #13}.

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

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

16. REFERENCES

Attachment 1

The Draize Scale 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 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