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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

C.I. Pigment Yellow 194

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

C.I. Pigment Yellow 194

1. APPLICANT

Hoechst Australia Limited of 606 St Kilda Road MELBOURNE VIC 3004 has submitted a standard notification statement in support of their application for an assessment certificate for C.I. Pigment Yellow 194.

2. IDENTITY OF THE CHEMICAL

C.I. Pigment Yellow 194 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, formulation details and details of exact import volume and customers have been exempted from publication in the Full Public Report and the Summary Report.

Other Names:	C.I. Pigment Yellow 194
Trade Names:	Novoperm Yellow F2G; Novoperm Gelb (Yellow) F2G-A; Pigment Yellow P-495; Pigment Yellow VP431
Molecular Weight:	> 300
Method of Detection and Determination:	UV/Visible spectroscopy; infrared spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	yellow powder
Melting Point:	> 250°C
Specific Gravity:	1.47
Vapour Pressure:	not applicable - notified substance is a solid

Water Solubility:	< 20 µg/L at 20°C (spectrophotometric method detection limit)
Partition Co-efficient (n-octanol/water):	not applicable - substance is insoluble in water
Hydrolysis as a Function of pH:	not applicable - substance is insoluble in water
Adsorption/Desorption:	no information available from the manufacturer
Dissociation Constant:	not provided (calculated value; log P_{OW} = 2.29 (1))
Particle Size:	280 nm (median)
Flash Point:	not applicable - notified substance is a solid
Flammability Limits:	not flammable
Autoignition Temperature:	no information available from the manufacturer
Explosive Properties:	possibility of dust explosion
Reactivity/Stability:	chemically stable; not known to have any hazardous reactions or incompatible substances; thermal decomposition under fire conditions may generate carbon monoxide, carbon dioxide and oxides of nitrogen

Comments on Physico-Chemical Properties

The notified powder is non-volatile and practically insoluble at room temperature. The negligible water solubility measured for this substance results from the lack of functionality that might confer such properties to this chemical.

While in one tautomeric form the notified substance contains an amide functionality, it is not expected to hydrolyse under environmental conditions due to its low solubility, which also precludes measurement.

Information on partition coefficient and adsorption/desorption was not supplied by the notifier. However a calculated value for log P_{ow} has been determined through a structural based calculation (1). This figure appears low when the water solubility is taken into account and may reflect low fat solubility also.

The substance is expected to sorb strongly, or be associated with soil or sediment, due to low solubility.

There are no groups likely to dissociate within this chemical.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 99%

Toxic or Hazardous Impurities: none

Non-hazardous Impurities (> 1% by weight): none

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

C.I. Pigment Yellow 194 will not be manufactured in Australia. The notified chemical is a pigment which will be imported and reformulated into powder coating products and liquid paint. Approximately 60% of the pigment will be used in powder coating products, where it will be at a final concentration of less than 8%. The powder coating preparations will be used for industrial coating of steel sheets and will not be available for public use. The remaining 40% of the imported pigment will be used in liquid paints (at concentrations of up to 10%) , which will be available for both industrial and public use.

It is estimated that no more than 5 tonnes of the notified chemical will be imported per year for the first 5 years.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported in 25 kg polyethylene bags within fibre board cartons and transported from dockside on shrink-wrapped pallets.

Waterside, warehouse and transport workers will handle containers of the imported chemical in its pure form, as well as powder coating and liquid paint products containing less than 8% and up to 10% of the notified chemical, respectively. These workers are unlikely to be exposed to the notified chemical under normal circumstances.

Powder coatings

The potential for dermal, inhalational and ocular exposure to the notified chemical exists for workers involved in reformulating the notified chemical into powder coatings. Reformulation involves weighing of the pigment powder prior to blending it with other substances. The potential for exposure is very high during weighing, given that the pigment is in its pure form and the median particle size of the powder is 280 nm. This particle size is considered to be more than 98% respirable according to the definition provided by Standards Australia (cited in (2)).

The powder coating mixture is then compounded, milled and packaged for distribution. As the notified chemical remains in powdered form at all stages of this reformulation process, the potential for dermal, inhalational and ocular exposure is high. The notifier did not provide a particle size distribution for the final powder coating products, however, another study indicated that 2.3% of the particles in a powder coating were in the respirable range, and that all of the particles had the potential to be inhaled (3). The notifier states that each of the processes involved in reformulation takes place under local exhaust ventilation, which is ducted to a central baghouse. Reformulators are expected to be potentially exposed to the notified chemical for 36 days per year.

The electrostatic application of the coating to metal surfaces is usually performed in a dedicated sealed off area, with totally automated application equipment. The powder coated panels are then heat cured. Overspray is reclaimed and fed back into the application hopper. If the spray processes are completely automated, inhalational, dermal and ocular exposure may only occur while workers are manually filling hoppers with the coating in powder form or cleaning the electrostatic application equipment and application booth. If a powder coating site is not fully automated, further exposure to the dust may occur during application. Applicators are expected to be potentially exposed to the notified chemical approximately 235 days per year.

Quality control personnel may be exposed to the notified chemical during the sampling of coating from batches and electrostatic application to test metal panels, which also takes place in a dedicated spray booth. Quality control personnel are expected to have intermittent exposure to the notified chemical in powder coating formulations for 36 days per year. Product development involves reformulation and quality control processes, but on a smaller scale. People working in product development may be exposed to the pure pigment and formulated containing the pigment for approximately 50 days per year.

Liquid paint

Liquid paint manufacturing personnel may be exposed to the notified chemical during reformulation. The potential for dermal, inhalational and ocular exposure to the notified chemical is highest among workers involved in weighing the notified chemical in powder form and predispersing the pigment into a resin/solvent mix using a high speed mixer. The notifier states that there is dust and vapour extraction on each mixer at this stage of the process. After this stage the notified chemical is part of a liquid system, thus reducing the potential for inhalational exposure. Dermal exposure may still occur, however, during dispersion of the pigment and completion of the product using other raw materials. Ocular exposure to the notified chemical in a liquid system is expected to be limited to accidents. This type of worker exposure to the pigment and products containing the pigment is estimated to be a maximum of 8 hours per day, 36 days per year.

Workers may be exposed to the notified chemical during application of liquid paint products containing the notified chemical. Spray paint applicators may be exposed by dermal and inhalational routes and ocular contact may also occur. The notifier states that spray painting of liquid paint products containing the notified chemical is often carried out in spray booths, in which the air flow minimises inhalation and

dermal exposure. If paints are applied by brush, dermal exposure is expected to be the main route of exposure, although accidental ocular contact may also occur. Should contact occur during application, the paint is likely to remain on the exposed surface for some time, hence prolonging exposure.

Product development and quality control personnel will be exposed to the notified chemical on an intermittent basis when developing new products or testing the physical properties and performance of a paint.

7. PUBLIC EXPOSURE

The powder coating products containing the notified chemical will be used at industrial sites only. Liquid paint containing the notified chemical will be used industrially, as well as being available to the general public for domestic use.

For industrial use, coating processes for both the powder and liquid forms will be performed within enclosed spray booths. For domestic use, the public may be exposed to the notified chemical by dermal contact when applying the paint or cleaning of painting equipment.

The general public may come into contact with the surface of coated products, but the notified chemical will be incorporated in the cured coating and will not be available for direct exposure.

Waste generated during reformulation and coating will be collected in extraction systems, and will be disposed of to landfill. Release of the notified chemical during reformulation or spray coating to the atmosphere is minimal. It is assumed that residues on painting equipment used in domestic situations are to be washed to the sewer.

Accidental spills will be collected and disposed of to land fill or by incineration. Because the notified chemical is insoluble in water, leaching of the notified chemical into ground water at land fill sites is not expected to occur.

Public exposure to the notified chemical from normal storage, transport, industrial use and regulated disposal is expected to be minimal.

8. ENVIRONMENTAL EXPOSURE

Release

Powder coatings

Formulation of the powder coating containing the notified substance will take place at three sites. The notifier has indicated that the maximum yearly loss from formulation will be negligible. Possible release to the environment will be to the atmosphere via exhaust ventilation (maximum 2 kg/day or < 0.02 kg of notified substance), release to sewers via waste water treatment (maximum 2.5 kg/day or

< 0.025 kg of notified substance) and to the terrestrial environment via landfill treatment of cleaning wastes. Treatment and disposal of any spillages is adequately dealt with in the Material Safety Data Sheet (MSDS).

Environmental exposure during the use of these powder coatings is likely. This is possible through emissions during application of these coatings to the various metal substrates within spray booths. Although these spray booths are closed systems, there is the likelihood of losses of notified substance during replacement of the recovery bags from the exhaust filter. Due to the fact that these losses are reblended and reused it has been estimated that these losses will amount to a maximum of 1.0% or 0.23 tonnes per year.

Liquid paints

Losses during liquid paint formulation are estimated by the notifier at 2-3%. Hence, based on maximum import volumes and 40% to be used in liquid paints, it would be expected that 60 kg of the new chemical could be lost during liquid paint formulation.
Reformulation equipment will be washed with wash solvent, which is sent to a solvent recycler for recovery. Equipment used at the other two sites will be washed with water and sent to an on-site water treatment plant for sedimentation and further processing. After the respective treatments, solids will be disposed of to an approved landfill site. Residues remaining in the chemical import containers are estimated by the notifier at 1%. These containers will be removed by waste disposal contractors.

Where the paint containing the notified chemical is applied through spray painting systems by automotive repair shops, up to 30% could be lost through overspray (up to 450 kg/year). This overspray is collected either in filters (dry booth) or in a water trap and coagulated (wet booth). Wastes are collected and disposed of according to waste disposal regulations, probably to a waste disposal contractor.

Paints for use in the domestic market are applied in the main by brushes and rollers, both by professional painters and do-it-yourself (D-I-Y) painters. No significant amounts of wastes are expected to be generated during application, as paints are said to be formulated to minimise the amount of brush drip and roller fly-off. Equipment will be cleaned in water (80% of cases) and in mineral turpentine (20% of cases) (this is the ratio of water-based to oil-based paints sold). The EPA expects that the majority of these washings will be sent to the sewer, with some lost to the surrounding ground near the wash-up site.

It is expected that residues in empty paint product containers used by professional painters will be minimised, with cans disposed of as industrial waste. The amount of residue left in cans supplied to D-I-Y painters is unknown, and depends on how close the amount purchased is to the amount of paint required. It is likely that some left over paint will be retained for future use. However, it is expected that ultimately paint cans and the associated residues will be disposed of through municipal waste collection systems to landfill.

Fate

The majority of the notified substance released to the environment from powder coatings would be via sewer and landfill emissions, with a minor component arising from release of the fine particulate powder coating to the atmosphere at either the formulation or final use stages. The latter material will be collected as trappings in filters, which will then be reblended or reused in the formulation process. In the case of water treatments organic solvents such as alcohols or water-based detergents are used, with the washings captured in drums for disposal according to local regulations. However, most is likely to be associated with sediment, which will be landfilled or incinerated.

The majority of notified chemical used in liquid paints is not expected to be released to the environment until it has been fully cured into the paint's solid polymer matrix. Waste paint resulting from overspray at automotive repair shops is also not expected to be released until it has been fully cured.

The fate of the notified chemical will be the same as the articles to which the paint/coating is applied. As part of a polymerised solid/coat, no hydrolysis, movement, biodegradation or bioaccumulation of the notified chemical is expected.

The proposed nature of usage of the notified pigment should ensure that minimal quantities of uncured product are released to the environment. The waste generated by use of the notified substance will be insoluble in water and, by analogy with a related compound, is expected to be insoluble in fat. Although the pigment is expected to be poorly biodegradable, it is believed that the bioaccumulation in the environment will not occur.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summaries of an acute oral study, skin and eye irritation studies, and an Ames test on the notified chemical were provided. The company could not obtain the full reports of these studies. Studies on another azopigment, Pigment Orange P9025, were provided. Based on the similarity of molecular structure and physico-chemical properties of the two azopigments, they are expected to have similar biological activities. Thus, studies on Pigment Orange P9025 may be used to support studies on the toxicity of the notified chemical.

Summary of acute toxicity:

Test	*Species*	*Outcome*	*Reference*
C.I. Pigment Yellow 194			
Acute oral toxicity	rat	LD_{50} > 5 000 mg/kg	(4)
Skin irritation	rabbit	non-irritant	(5)
Eye irritation	rabbit	slight irritant	(5)
Pigment Orange P9025			
Acute oral toxicity	rat	LD_{50} > 2 000 mg/kg	(6)
Acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	(7)
Eye irritation	rabbit	slight irritant	(8)
Skin sensitisation	guinea pig	non-sensitising	(9)

9.1.1 Oral Toxicity (4,6)

C.I. Pigment Yellow 194 (4)

Ten female Wistar rats, Hoe WISKf(SPF71) strain, were administered 5 000 mg/kg C.I. Pigment Yellow 194 suspended in purified water at 12.5% by a single oral gavage and observed for 14 days prior to necropsy. There were no deaths or clinical signs of toxicity. Pigmented urine and faeces were observed. Body weight gain was normal. No gross lesions were found at necropsy. The oral LD_{50} of C.I. Pigment Yellow 194 was greater than 5 000 mg/kg.

Pigment Orange P9025 (6)

Ten (5/sex) Wistar rats, Hoe WISKf(SPF71) strain, 7 - 8 weeks of age, were administered 2 000 mg/kg Pigment Orange P9025 suspended in sesame oil by a single oral gavage and observed for 14 days prior to necropsy. There were no deaths or clinical signs of toxicity. Pigmented faeces were observed in the first 3 days after dosing. Body weight gain was normal. No gross lesions were found at necropsy. The oral LD_{50} of Pigment Orange P9025 was greater than 2 000 mg/kg.

9.1.2 Dermal Toxicity (7)

Pigment Orange P9025

Ten (5/sex) Wistar rats, Hoe WISKf(SPF71) strain, 8 - 9 weeks of age, were dermally treated with 2 000 mg/kg Pigment Orange P9025 in water on the intact skin under occlusive dressing (foil) for 24 hours. The animals were observed for 14 days before necropsy. No deaths occurred. The application site was orange in colour in the first 7 days, but no signs of systemic toxicity were observed. No gross lesions were found at necropsy. The dermal LD_{50} of Pigment Orange P9025 in rats was greater than 2 000 mg/kg.

9.1.3 Inhalation Toxicity

No studies were submitted.

9.1.4 Skin Irritation (5)

C.I. Pigment Yellow 194

Six albino Himalayan rabbits, Hoe:HIMK (SPFWiga) strain (1.9 - 3.4 kg), were dermally treated with 0.5 g of C.I. Pigment Yellow 194 moistened with 1.2 mL physiological saline on the intact skin under a cellulose pad and impermeable polyethylene foil (occlusive dressing) for 24 hours. The animals were examined immediately, and at 47 and 71 hours after patch removal. The irritation was scored according to the method described in the USA Federal Register (10).

The mean irritation index was 0.3. Individual irritation scores were not provided in the report. The test substance was not a skin irritant in rabbits.

9.1.5 Eye Irritation (5,8)

C.I. Pigment Yellow 194 (5)

Six rabbits received 0.1 g of C.I. Pigment Yellow 194 moistened with 0.2 mL physiological saline into the conjunctival sac of the left eye. The eyes were washed with physiological saline at 24 hours after dosing. The eyes were examined at 1, 7, 24, 48 and 72 hours after application, and scored according to the FDA (USA) guideline (11). The highest score of 11 was recorded at 1 hour after dosing. Individual scores were not provided. C.I. Pigment Yellow 194 was a slight eye irritant in rabbits.

Pigment Orange P9025 (8)

Three NZW albino rabbits (3 - 5 months of age) received 0.1 g of Pigment Orange P9025 into the conjunctival sac of the left eye. The eyes were washed with physiological saline at 24 hours after dosing. The eyes were examined at 1, 24, 48 and 72 hours after application, and scored according to the OECD guideline (12).

All the animals exhibited slight to moderate redness and swelling of the conjunctivae from 1 to 48 hours after treatment. Slight congestion of the iris of one rabbit was seen at 24 hours. Orange coloured discharge was observed, but disappeared 3 days after dosing. The mean irritation index (24, 48 and 72 hours) was 0.1 for iris effects, 1.0 for conjunctival redness and 0.4 for conjunctival swelling. The test substance was a slight eye irritant in rabbits.

9.1.6 Skin Sensitisation (9)

Pigment Orange P9025

The skin sensitisation potential of Pigment Orange P9025 was studied in female Pirbright-White guinea pigs using the guinea pig maximisation test (GPMT).

In the preliminary irritation test, two guinea pigs were dermally treated with 0.5 g of 1, 5 and 15% of Pigment Orange P9025 in petrolatum onto the left flank under occlusive dressing for 24 hours. No signs of irritation were seen at the two low doses. One animal at 15% exhibited slight redness and both animals showed a light orange discolouration at 24 hours after patch removal.

Three guinea pigs were intradermally injected twice with 0.1 mL of 0.2, 1 and 5% of test substance in semi-liquid paraffin (time interval of the two injections not reported). Slight to moderate erythema and oedema were observed at the sites injected with 1 or 5% of test substance. The injection site at 0.2% of test substance showed very slight erythema and oedema. All the injection sites had orange discolouration.

After the preliminary irritation test, a group of 10 guinea pigs were intradermally injected twice, in the dorsal region, with 0.1 mL 50% Freund's adjuvant (FA), 1% of test substance in semi-liquid paraffin, and 1% test substance in 50% FA.

Seven days after intradermal treatment, the animals were dermally treated with 0.5 g test substance in petrolatum on the injection sites using the method as described in the preliminary irritation test but for a 48 hours exposure period.

Two weeks after topical induction exposure, the animals were challenged with 5% of test substance in petrolatum by dermal application using the method as described in the preliminary test. The skin reaction was examined at 24 and 48 hours after patch removal.

A vehicle control group of 5 animals was similarly treated with the exception that test substance was not used in the induction exposure. No positive controls were used in the study.

After intradermal induction exposure, the injection sites showed slight to moderate erythema and oedema, and orange discolouration. Eschar formation and necrosis were seen 10 days after treatment. No irritation reactions were observed after challenge in the control and test groups, although orange discolouration was seen in all the animals. Pigment Orange P9025 was not a skin sensitiser in guinea pigs.

9.2 Repeated Dose Toxicity (13)

Pigment Orange P9025

Wistar rats (5/sex/group) were orally administered 0, 62.5, 250 or 1 000 mg/kg/day Pigment Orange P9025 in sesame oil by gavage for 28 days. Clinical signs, body weight, feed consumption and organ weights were recorded. Haematology, clinical chemistry, urinalysis, gross necropsy and histopathology were performed. The parameters examined are listed in Appendix A.

Orange discolouration of the faeces occurred in the 1 000 mg/kg/day groups of both sexes. One male had diarrhoea on days 14, 16 and 17. All treated female groups had significantly reduced red blood cell (RBC) and packed cell volume (PCV) parameters compared with the control group. These changes were not observed in any male groups. No mortalities occurred during the study. There were no treatment-related changes in body weight gain, feed consumption, urinalysis, clinical chemistry, or organ weights. No treatment-related macroscopic or microscopic changes were detected.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (14, 15)

C.I. Pigment Yellow 194 (14)

Salmonella typhimurium strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538 were cultured with 4 - 2 500 μg/plate of C.I. Pigment Yellow 194 in DMSO with and without metabolic activation using rat liver S9. Each concentration was tested in triplicate.

The number of revertants was comparable between the vehicle control and test groups. The positive controls were adequate. Under the condition of the assay, C.I. Pigment Yellow 194 was not mutagenic in the *Salmonella typhimurium* reverse mutation assay.

Pigment Orange P9025 (15)

Salmonella typhimurium strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538, and *Escherichia coli* WP2*uvrA* were cultured with 4 - 2 500 μg/plate of Pigment Orange P9025 in DMSO with or without metabolic activation using rat liver S9. Each concentration was tested in triplicate. A confirmatory study was conducted.

The number of revertants was comparable between the vehicle control and test groups. The positive controls were adequate. Under the condition of the assay, Pigment Orange P9025 was not mutagenic in the *Salmonella typhimurium* and *Escherichia coli* reverse mutation assay.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (16)

Pigment Orange P9025

NMRI mice (15/sex/group) at 8 weeks old were orally administered 0 or 1 500 mg/kg of Pigment Orange P9025 in sesame oil. A positive control group (5/sex) received 50 mg/kg of cyclophosphamide. Bone marrow was collected from 10 animals (5/sex) from each treatment and vehicle control group at 24, 48 and 72 hours after administration. Positive controls were sampled at 24 hours. Bone marrow smears were examined and 1 000 polychromatic erythrocytes were scored for micronuclei.

Orange coloured urine and faeces were observed in the treated animals. No gross changes were seen at necropsy. Micronucleus frequencies were comparable between the vehicle control and treated groups. The positive controls had markedly increased micronucleus frequency. Pigment Orange P9025 was not considered to cause chromosomal damage in bone marrow cells of the mouse *in vivo*.

9.4 Overall Assessment of Toxicological Data

Based on the toxicity studies, the notified chemical was of low acute oral toxicity in rats with a LD_{50} greater than 5 000 mg/kg. It was not a skin irritant, but was a slight eye irritant in rabbits. Toxicity studies on Pigment Orange P9025 suggested that the notified chemical may be of low acute dermal toxicity in rats and is unlikely to be a skin sensitiser in guinea pigs. Reduced RBC and PCV were observed in female rats given Pigment Orange P9025 orally at doses in excess of 62.5 mg/kg/day for 28 days, but these changes were not seen in male rats. Based on these results, the notified chemical may also have low toxicity by repeated oral administration. Pigment Orange P9025 did not induce reverse mutation in bacterial assays *in vitro* or in mice bone marrow micronuclei when tested *in vivo*. The notified chemical was also not mutagenic in the Ames test, and is unlikely to induce genotoxic effects.

Based on the information summarised above, the notified chemical would not be classified as hazardous according to Worksafe Australia's *Approved Criteria for the Classification of Hazardous Substances* (17).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been provided by the notifier. These studies were carried out on the chemical, Pigment Orange P 9025, which is close to a dimer of Novoperm Yellow F2G. This expected to be even less soluble. The tests were carried out according to OECD Test Methods.

Test	*Species*	*Results*
acute renewal toxicity	zebra fish (*Brachydanio rerio*)	96 hour LC_{50} > 500 mg/L (18)
acute immobilisation	daphnid (*Daphnia magna*)	48 hour EL_{50} > 1 000 mg/L* (19)

*Effective loading is the calculated loading level which results in 50% immobilisation in a population during a specified period

For the toxicity tests on zebra fish, the emulsifying agent TWEEN 80 was used to allow solubilisation of the notified substance to concentrations required for the investigation.

Acute toxicity was tested on zebra fish (18) according to OECD guideline 203 (12). The nominal concentrations tested were 500 mg/L and a negative control at 0 mg/L. During 96 hr periods of exposure of the notified substance to zebra fish, no mortality was observed at either concentration.

Acute immobilisation was tested by exposure of *Daphnia* to the notified substance (19) according to OECD guideline 202 (12). Using the emulsifying agent TWEEN 80, test concentrations of 1 000 mg/L, 500 mg/L, and 320 mg/L were made of the notified substance. The 48 hr effective loading (EL_{50}) for these tests were greater than 1 000 mg/L.

No results for toxicity to algae were provided, but this is acceptable due to expected limited contamination of the aquatic compartment.

The levels measured by the above tests, suggest the notified substance would be considered non-toxic to the organisms tested, up to the level of its solubility or dispersability.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified substance is unlikely to present a hazard to the environment at any stage of its use as a powder coating. It is expected that negligible amounts will be released from the powder coating formulation sites and the ultimate fate of the waste pigment is treatment by landfill at an approved industrial facility. Leaching of such treated wastes into the soil is not expected.

Of the maximum imported quantity to be used in liquid paints, it is expected that 60 kg will be released from the formulation sites. Up to 450 kg/year of notified chemical will be lost to the environment through the disposal of overspray from automotive repair shops. However, the waste paint will be treated by contractors, with the cured solid being disposed to landfill. Quantities released to the environment from D-I-Y users are unknown. However, the volume identified for this market is relatively small (ie 500 kg/year Australia-wide). Waste paint will be either

stored for future use, sent to the sewer, or disposed of to the ground surrounding the wash-up area. The chemical is not expected to leach, instead becoming immobile on association with soil/sediment.

The ultimate fate of the waste pigment is treatment by landfill at an approved industrial facility. Leaching of such treated wastes into the soil is not expected.

Overall, spills are unlikely to result in widespread exposure, and together with low expected ecotoxicity and low aqueous solubility the potential hazard to the environment should be negligible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The occupational health risk posed to waterside, warehouse and transport workers (who may handle the notified chemical in pure form or products containing the notified chemical) is negligible, based on the expected lack of exposure and the low toxicity and low irritancy of the notified chemical and a related pigment.

Powder coatings

There is a low occupational health risk to workers involved in reformulating the notified chemical into powder coating products. The potential for exposure to the notified chemical is high, due to the fine powder nature of the pure substance, and the powdered nature of the final products. The notifier states that exposure to the notified chemical and other components of the powder coatings will be reduced by local exhaust ventilation, which will be present at all stages of the reformulation process. Animal studies indicate that the notified chemical and a related pigment are of low acute toxicity. The notified chemical is likely to be of low irritancy and it is not mutagenic *in vitro* and *in vivo*. Analogue data indicates that the notified chemical is of low toxicity when orally administered to rats for a 28 day period. However, inhalational toxicity data is not available for the notified chemical, and as the potential for inhalational exposure to the notified chemical (both in pure form and in powder coating products) is high, personal protective equipment should be worn to minimise exposure (see recommendations section). In addition, the level of dust in the workplace should be controlled according to Worksafe Australia's exposure standard for nuisance dusts (10 mg/m^3)(2).

There is also a low occupational health risk for powder coat applicators, who may be exposed to the notified chemical at concentrations of up to 8%. The notifier states that powder coating is usually carried out in fully automated spray booths, thus limiting worker exposure to periods when hoppers are being refilled, or equipment is being cleaned. Dermal or ocular contact is unlikely to result in adverse health effects, however, appropriate precautions should be taken to minimise inhalational exposure to the notified chemical in powder coating products, for the reasons outlined in the preceding paragraph. Workers should also be aware of any potentially hazardous components that are present in powder coating products.

Quality control and product development personnel may also be exposed to the notified chemical, but the occupational health risk is low, due to the expected intermittent exposures and the toxicity profile of the chemical.

Public exposure to the notified chemical is expected to be negligible as a result of industrial use in powder coating products. Any accidental public exposure is unlikely to cause adverse health effects.

Liquid Paint

There is a low health risk to reformulators who will be handling the notified chemical in powdered form prior to incorporation into liquid paint systems for the reasons discussed above.

Once the pigment is incorporated into liquid paints, the occupational health risk posed to workers who handle these paints (either during reformulation/ packaging or during end use) is also low, due the expected low toxicity (discussed above) and the relatively low (< 10%) levels of the notified polymer in paint products. Worker exposure to paints containing the notified polymer may, however, be frequent and prolonged.

The public may be dermally exposed to liquid paint containing up to 10% of the notified chemical. However, toxicological studies on the notified chemical and a similar azopigment indicate that the notified chemical is of low acute toxicity and is not mutagenic. Short periods of dermal contact with liquid paints containing the notified chemical is not expected to cause significant health effects.

13. RECOMMENDATIONS

To minimise occupational exposure to C.I. Pigment Yellow 194 the following guidelines and precautions should be observed:

- A mask which conforms to Australian/New Zealand Standard (AS/NZS) 1715-1994: *Use and Maintenance of Respiratory Protective Devices* (20) and AS/NZS 1716-1991: *Respiratory Protective Devices* (21) should be worn if engineering controls are inadequate, to reduce inhalational exposure to the notified chemical to a safe level (both in pure form and in powder coating products);

- Industrial clothing should conform to the specifications detailed in AS 2919 (22);

- All occupational footwear should conform to AS/NZS 2210 (23);

- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly and put into containers for disposal in accordance with Local, State and Federal government regulations;

- Good personal hygiene should be practised to minimise the potential for ingestion;

- The Worksafe Australia document *Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards* (2) should be used as a guide to the monitoring and control of any nuisance dusts generated while handling pure C.I. Pigment Yellow 194 or products containing the notified chemical;

- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (24).

This MSDS was provided by the notifier as part of the notification statement. The accuracy of this information remains the responsibility of the notifier.

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. Secondary notification under subsection 64(1) of the Act will be required if the uses proposed would lead to greater contamination of the aquatic compartment. These should include full physico-chemical data and aquatic toxicity results for the notified chemical.

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Appendix A

Test Parameters

Clinical Chemistry	Haematology	Urinalysis	Organs weighed	Histology
alanine aminotransferase	coagulation time	appearance	adrenals	adrenals
albumin	haemoglobin (Hb)	bilirubin	heart	colon
alkaline phosphatase	Heinz bodies	glucose	kidneys	femur bone marrow
aspartate aminotransferase	mean corpuscular haemoglobin	ketones	liver	heart
bilirubin, total	mean corpuscular volume	occult blood	lungs	jejunum
calcium	mean corpuscular haemoglobin concentration	pH	spleen	kidneys
chloride	packed cell volume (PCV)	protein	testes	liver
creatinine	platelet count	sediment		lungs
gamma-glutamyl transpeptidase	red cell morphology	specific gravity		spleen
glucose	red cell count (RBC)	urobilinogen		stomach
phosphorous, inorganic	reticulocyte count	volume		testes
potassium	white cell count			thymus
protein, total	white cell differential			
sodium				
urea nitrogen				
uric acid				

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