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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Hostaperm Yellow H5G

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**Director
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FULL PUBLIC REPORT

HOSTAPERM YELLOW H5G

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT

Clariant (Australia) Pty Ltd
675 Warrigal Road
Chadstone, Vic 3148
ABN: 30 069 435 552

NOTIFICATION CATEGORY

Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Spectral Data, Purity, Hazardous and Non-hazardous Impurities, Details of Introduction and Use Information, Distribution and Details of Occupational Exposure.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Adsorption/Desorption

Acute inhalation toxicity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None.

NOTIFICATION IN OTHER COUNTRIES

EU ID 99 04 1166 00 (30.3.2000)

USA EPA Case number: 2000-0084 (23.10.2000)

2. IDENTIFICATION OF CHEMICAL

OTHER NAME

C.I. Pigment Yellow 213

MARKETING NAME(S)

Hostaperm Yellow H5G, Hostaperm Gelb H5G, Novoperm Yellow H5G, Novoperm Gelb H5G

3. COMPOSITION

DEGREE OF PURITY

High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

None

4. INTRODUCTION AND USE INFORMATION

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

The notified chemical will not be manufactured in Australia. It will be imported either as a component of the pigment product, Hostaperm Yellow H5G (>95% active), or as a component of formulated paints (<10% notified chemical).

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

Volume of chemical imported would be <10 tonnes per annum over the next 5 years.

USE

Colourant for the manufacture of automotive and industrial paints and lacquers.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY

Melbourne and Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS

Clariant (Australia) Pty Ltd
675 Warrigal Road
Chadstone Vic 3148

TRANSPORTATION AND PACKAGING

The notified chemical is not classified as dangerous goods and may be transported with general industrial chemicals. The technical grade notified chemical (as a constituent of Hostaperm Yellow H5G) will be packaged in 10 kg or 20 kg multi-layer paper bags in fibreboard boxes.

The formulated paint products will be filled into 1, 2, 4, 10 or 20 litre steel or plastic cans or pails with pressure fit lids or clamp lids.

5.2. Operation description

The notified chemical, imported as pigment product, will be used in routine weighing/ blending/ milling/ mixing/ testing/ filling operations as part of the regular program by paint manufacturers producing a range of paint formulations. The imported technical grade notified chemical will be initially stored in Clariant (Australia) Pty Ltd stores, then despatched to companies for use in production of paint coatings.

For the manufacture of paints, the notified chemical is blended with other ingredients to make the final paint product. The procedure involves weighing, transferring, milling, mixing and testing operations.

The formulated paint products will be filled into steel or plastic cans or pails with pressure fit lids or clamp lids and sent to contract warehouse for storage and distribution to automotive refinish suppliers.

The packaged paint products will be distributed through wholesalers to spray painting/smash repair or industrial trade customers, who are the main end-users. During industrial and automotive application of paints, spraying is carried out in spray booths. The paint products will be spray applied by both manual spray and automatic electrostatic atomised spray techniques to car bodies and to industrial equipment.

After the paint application is complete, the spray gun and lines will be emptied and any residual paint will be placed into a "paint waste" drum for recycling. The spray gun is then cleaned at an earthed recycled solvent wash station. The spray equipment is then cleaned and ready for the next job.

5.3. Occupational Exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration hours per day</i>	<i>Exposure Frequency days per year</i>
Warehouse/Distribution		<1	10
Paint manufacture operators	30-45	<4	10
Quality Control personnel	6-10	<1	10
Technical Service/ Development Chemists	8-20	<4	<10

Exposure Details

Standard controls and procedures are used in handling of similar pigments ensuring that worker exposure to the notified chemical is minimised during paint manufacture. For handling of the chemical and paint, the minimum protection would be impervious gloves, coveralls and goggles. Warehousing and distribution of the notified chemical involves moving and storing packaged pigment products or packaged formulated paint products containing the notified chemical at <10%.

Paint manufacture operators will be involved in retrieval of pigment from stores, weighing and addition of the notified chemical to paint batch mixing vessels, supervision of paint mixing and supervision of filling of paint products into steel or plastic cans or pails with pressure fit lids or clamp lids.

During manufacture of paints, operations to weigh and add raw materials, including the notified chemical, to the paint batches are carried out under a mechanical ventilation system that creates a flow of air away from operators. The ventilation system is primarily a requirement because of the presence of solvents in many of the paint raw materials.

Paint manufacture employs the use of mixers fitted with exhaust ventilation to capture volatiles at source. Paint manufacture operators wear protective gloves and wear eye protection where necessary when handling pigment products and supervising paint manufacture. As well as the above protective equipment, personnel wear long-sleeved industrial clothing and safety boots and follow good workplace hygiene and housekeeping practices.

Quality control personnel will be required to collect samples (approximately 500 g) of paint batches to evaluate performance characteristics of the batches. Personnel involved in quality control procedures are required to wear laboratory coats, safety glasses/goggles, protective gloves and safety boots as appropriate to the particular tasks.

Technical service and development chemists will be involved in laboratory development of paint formulations with possible follow up laboratory trials to investigate performance characteristics of the formulations.

5.4. Release

RELEASE OF CHEMICAL AT SITE

Environmental exposure associated with the manufacture of the notified chemical will not occur in Australia as this takes place overseas. During the weighing and bag-emptying process, a handling loss of <1% can occur with pigment powder trapped in the dust extraction filter system. Consequently, up to 100 kg per 12 months maximum may be extracted by the filter system.

The combined dust residues are disposed in closed bags to regulated landfills. Residual pigment powder may remain in emptied packaging of the product Hostaperm Yellow H5G. It is estimated that up to 50 g of notified chemical powder (0.25%) may remain in each 20 kg package, which adds up to a maximum of 25 kg per 12 months. The packaging will be disposed of in packaging through a licensed waste disposal contractor.

For the processes involving liquid paint formulations, loss of up to 1.5% of paint batches may occur after draining and cleaning of mixing vessels and equipment. Accordingly, up to 150 kg of notified chemical may be collected during cleaning operations for reuse or disposal via licensed waste disposal contractors. It is possible that accidental spillage may occur during production/ packaging. Liquid paint spills are contained on site by bunding and retained until reprocessed or disposed of by approved contractors.

The total amount of notified chemical potentially released from manufacturing is the sum of 100 kg from empty bags, 25 kg from dust and 150 kg from cleaning which equals 275 kg per 12 months.

RELEASE OF CHEMICAL FROM USE

It is estimated that the volume of paint manufactured and imported into Australia will be used approximately 66% for industrial or automotive use at over 500 sites throughout Australia and the remainder for domestic use by both professional painters and by members of the public.

During industrial and automotive application of paints, spraying is carried out in spray booths. The paint products will be spray applied in spray booths by both manual spray and automatic electrostatic atomised spray techniques to car bodies and to industrial equipment.

Transfer efficiencies will be approximately 35% for hand spray and 80% for the automatic method. The resultant overspray is collected in the spray booth water, and then chemically treated in water scrubbing systems. As a result, the notified chemical itself does not represent an emission hazard to the atmosphere. The paint material, which is removed by the scrubbers, is separated out using flotation techniques. The separated sludge is then removed for incineration by licensed waste removal contractors.

Paint waste containing the notified chemical will be generated from three main areas:

- (i) Overspray from the application process
- (ii) Flushing and cleaning of application and mixing equipment
- (iii) Empty paint containers.

Average transfer efficiency is estimated as 75% for the combined manual and automated electrostatic application equipment in use. It is estimated that 90% of the paint is applied by the automatic sprayers and 10% applied by manual guns. Therefore, on average, 25% of the paint, and hence the notified chemical is lost through overspray. This loss is estimated to be up to 1650 kg per annum. This overspray is collected by the spray booth air and water filtration systems. Cleaning of the waste from spray booths will be carried out by licensed waste disposal contractors. The waste is taken off site for incineration.

Cleaning of application and mixing equipment will generate waste paint, which is collected and treated in the same way as spray booth waste. It is estimated up to 600 kg of the notified chemical will be contained in waste generated in this operation. So the total amount of notified chemical as a constituent of paint potentially going to landfill from use is a maximum of 2250 kg per 12 months.

A proportion of the notified chemical will be incorporated into architectural paints. These paints will be used at a large number of sites throughout Australia because of the potential use of decorative paints by professional painters and by members of the public.

It is estimated that less than 1% of formulated paint products will remain in the paint containers used by professional painters after the cans are drained for paint application. Consequently, a total of up to 33 kg of the notified chemical will remain as part of the paint residue distributed across a large number of emptied cans. The small quantity of residue of the chemical in each can will become bound in the hardened paint film. The notified chemical will be present at <10% in the paint film residues.

Paints containing the notified chemical will be used by professional painters as well as by the general public. Brushes, rollers and paint trays used for painting with alkyd or oil based paints will require cleaning with mineral turpentine or paint thinners whilst water based emulsion paint equipment would be washed with water.

Waste generated from these clean up operations, including empty paint cans, is estimated to amount to a loss of 1-2% of the paint products containing the notified chemical. This would amount to a total loss

of approx. 66 kg per year of the chemical.

Liquid wastes arising from cleaning operations are expected to be discharged to the sewer in a highly diluted form or spread over soil in domestic locations. Empty cans containing dried paint residues will most likely be disposed of to household refuse sites or industrial landfill sites at many locations throughout Australia.

As the end use of decorative paint products containing the notified chemical is destined for interior and exterior architectural surfaces, the ultimate release to the environment of the notified chemical will depend on the fate of the substrate to which the paint has been applied. Such substrates are expected to have a lifespan of 10-50 years plus. Redecorating or demolition could release the notified chemical to the environment via incineration or landfill.

5.5. Disposal

It is intended that all of the notified chemical will be incorporated into paint products. The need for disposal of the notified chemical will be limited and would only be required if spillage occurred or when residual so dust is collected from ventilation systems after paint manufacture.

Disposal of the notified chemical product should be in accordance with government regulations. It is recommended that disposal should be through a licensed waste disposal contractor to an approved landfill site or by incineration in an approved incinerator.

Waste from the paint manufacturing process and dust collected from fabric filter dust collectors will be contained in heavy walled polyethylene bags to minimise any loss to environment. This will be disposed of at approved landfill sites. It is estimated that the amount of notified chemical disposed of in this manner will be approximately 100 kg annually.

It is intended that the finished paint products containing the notified chemical will be sprayed onto industrial products and automotive vehicles or onto architectural surfaces. The disposal of any spillage of paint products will be either through a licensed waste disposal contractor to a regulated landfill or by incineration in an approved incinerator.

Residues of paint remaining in drums/cans after emptying cannot be estimated. However, the residues containing the notified chemical will cure in the containers. The containers are expected to be disposed of to regulated landfills.

5.6. Public exposure

The potential for exposure of the public to the notified chemical during industrial storage, handling and transportation is minimal. The packaging (multi-layer paper sacks in fibreboard cartons) will protect the contents from being released during normal handling. Only in extreme cases of inappropriate handling, or accidents during transportation, would there be any likelihood of the notified chemical product being released from the packaging for exposure to the public or for contamination of the environment.

Any routine exposure of the general public to the notified chemical will be as a component of cured paints on automobiles or as protective coatings on industrial products or as decorative paints for domestic use.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Yellow powder.

Melting Point/Freezing Point >330°C

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Differential scanning calorimeter was used for the test. Melting of the notified

TEST FACILITY	chemical was not observed. Reaction or decomposition occurred at temperatures above 330°C. NOTOX B.V (1999a)
Density	1520 kg/m ³ at 20°C
METHOD	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Density determined using a gas comparison pycnometer.
TEST FACILITY	NOTOX B.V (1999b)
Vapour Pressure	1.0 x 10 ⁻¹⁵ kPa at 25°C
METHOD	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	The boiling point of the test substance, which is necessary for the calculation of the vapour pressure, was calculated using Meissner's method. Using the calculated boiling point of the test substance (798° K), the vapour pressure was calculated using the Modified Watson Correlation.
TEST FACILITY	NOTOX B.V (1999c)
Water Solubility	<20 µg/L at 20°C
METHOD	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	A test based on the flask method was performed. An excess of the notified chemical was stirred with water for 7 hours at 80°C to achieve saturation. Subsequently, the solution was stirred for 64 hours at 20 ± 1°C to reach equilibrium. During the equilibrium period, a sample was taken from the water phase at 16, 40 and 64 h. Each sample was centrifuged four successive times. The concentration of notified chemical in all four centrifuged samples was determined to be <20 µg/L.
TEST FACILITY	NOTOX B.V (1999d)
Hydrolysis as a Function of pH	Not determined
Remarks	Study could not be performed due to low water solubility of the test substance. The notified chemical contains several functional groups which could hydrolyse but this is not expected under normal environmental conditions (ambient temperature and pH 4-9).
Partition Coefficient (n-octanol/water)	log Pow at 20°C = -1.5
METHOD	OECD TG 117 Partition Coefficient (n-octanol/water). EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks	Generally, the partition coefficient can be estimated from the n-octanol solubility and from the water solubility. The water solubility for the test substance was < 20 µg/L. The n-octanol solubility for the test substance was determined to be < 40 µg/L (using a method very similar to water solubility above). Because both solubilities are "smaller than" values, no partition coefficient could be calculated. Also, HPLC could not be used because the test substance was not soluble in the solvents used in HPLC. The partition coefficient was therefore calculated using the Rekker calculation method. Such methods are based on the theoretical fragmentation of the molecule into suitable substructures for which reliable log Pow increments are known. The log Pow is obtained by summing the fragment values and the correction terms for intramolecular interactions. In general, the reliability of calculation methods decreases as the complexity of the compound under study increases. This appears to be the case here as the calculated result indicates a clear preference for the aqueous phases, which is clearly not in line

with the very low water solubility. However, little detail of the method is given other than a computer program was used.

TEST FACILITY NOTOX B.V (1999e)

Adsorption/Desorption Not determined

Remarks No data is available for adsorption/desorption in standard soils. The notified chemical is an insoluble pigment and would be expected to associate with the soils and sediment phase in spite of a low Pow.

Dissociation Constant Not determined

Remarks Study could not be performed due to low water solubility of the test substance. The notified chemical does not contain any functional groups, which would be expected to dissociate under normal environmental conditions (pH 4-9).

Particle Size <1.2 µm

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

<i>Range (µm)</i>	<i>Mass (%)</i>
<1.2	100

Remarks The substance was dispersed in ethanol and the particle size distribution determined using laser diffraction.

TEST FACILITY NOTOX B.V (1999f)

Flash Point Not determined.

Remarks Not applicable for a solid

Flammability Limits Not highly flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).

Remarks Substance could not be ignited. Although it emitted sparks and burned in contact with ignition source, after removal of the source, the flame extinguished.

TEST FACILITY NOTOX B.V (1999g).

Autoignition Temperature Not self ignitable.

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.

Remarks No self-ignition at oven temperature of 340°C and substance temperature of 385°C.

TEST FACILITY NOTOX B.V (1999h).

Explosive Properties Not explosive.

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.

Remarks Does not contain any chemically unstable or highly energetic groups that might lead to an explosion.

TEST FACILITY NOTOX B.V (1999i).

Reactivity When handled and stored appropriately no dangerous reactions are known.

Oxidizing Properties No oxidizing properties.

METHOD EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).

Remarks Due to deficiency of oxygen, which gives a negative oxygen balance

TEST FACILITY NOTOX B.V (1999j).

7. TOXICOLOGICAL INVESTIGATIONS

<i>Endpoint and Result</i>	<i>Assessment Conclusion</i>
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 >2000 mg/kg bw	low toxicity
Rat, acute inhalation	No toxicity data were submitted
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation.
Rat, oral repeat dose toxicity – 28 days.	NOAEL 1000 mg/kg/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Mammalian Chromosomal	non genotoxic
Aberration Test.	
Genotoxicity – in vivo	No toxicity data were submitted

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/ Wistar Cr1: (WI) BR (outbred, SPF-quality)
Vehicle	Water
Remarks - Method	No significant protocol deviations

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	3 / female	2000	0
2	3 / male	2000	0

LD ₅₀	>2000 mg/kg bw
Signs of Toxicity	Yellow faecal staining was seen in all animals on day 2.
Effects in Organs	Stomach, thickening of limiting ridge noted in one female
Remarks - Results	None

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

TEST FACILITY NOTOX B.V (1999k).

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal).
Species/Strain	Rat/ Wistar Cr1: (WI) BR (outbred, SPF-quality)

Vehicle	Water
Type of dressing	Occlusive.
Remarks – Method	No significant protocol deviations

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
1	5 / male	2000	1
1	5 / female	2000	0

LD ₅₀	>2000 mg/kg bw
Signs of Toxicity - Local	Focal erythema in treated skin area of one female on day 7. Red staining of the skin in several animals immediately upon treatment. Yellow staining of the skin from day 2 onwards.
Signs of Toxicity - Systemic	Lethargy, tremors and/or ptosis of the eyes noted in 2 animals on day 2. Red staining in the neck and on the snout and head.
Effects in Organs	Dark red foci in the thymus and a watery fluid in the abdominal cavity of the animal that died during the study.
Remarks – Results	The death of one male was considered mainly to be caused by the dermal treatment with the test substance. The organ effects noted in this animal were considered agonal by the study authors.

CONCLUSION	The notified chemical is of low toxicity via the dermal route.
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TEST FACILITY	NOTOX B.V (1999l).
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7.3. Acute toxicity – inhalation

Data on inhalation toxicity was not provided. The notifier states that the physico-chemical and toxicological properties of the notified chemical indicate that its potential for absorption through dermal or inhalation routes is very low. The notified chemical is insoluble in water and fat and oral toxicity studies with the chemical indicated no evidence that it is absorbed from the gastro-intestinal tract.

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Vehicle	Water
Observation Period	72 h
Type of Dressing	Semi-occlusive.
Remarks – Method	No significant protocol deviations

RESULTS

<i>Lesion</i>	<i>Mean Score* Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema/Eschar</i>	0	0	0	1	<24 h	0
<i>Oedema</i>	0	0	0	0	0	0

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

Remarks – Results	Slight erythema occurred in treated skin areas of the 3 rabbits 1 hour after application only. No symptoms of systemic toxicity were observed and no mortality occurred. Yellow staining was observed throughout the study.
CONCLUSION	The notified chemical is non-irritating to skin.
TEST FACILITY	NOTOX B.V (1999m).

7.5. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 h
Remarks – Method	No significant protocol deviations

RESULTS

<i>Lesion</i>	<i>Mean Score* Animal No.</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	0.3	0.3	0.3	2	<48h	0
<i>Conjunctiva: chemosis</i>	0	0	0	1	<24h	0
<i>Conjunctiva: discharge</i>	0	0	0	1	0	0
<i>Corneal opacity</i>	0	0	0	0	0	0
<i>Iridial inflammation</i>	0	0	0	1	<24h	0

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

Remarks – Results	Iridal irritation occurred in one animal 1 hour after installation only. Conjunctival irritation consisted of redness, chemosis and discharge which completely resolved within 48 hours in all animals. No staining of ocular tissues was reported.
CONCLUSION	The notified chemical is non-irritating to the eye.
TEST FACILITY	NOTOX B.V (1999n).

7.6. Skin sensitisation

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 406 Skin Sensitisation - Maximisation test. EC Directive 96/54/EC B.6 Skin Sensitisation - Maximisation test.
Species/Strain	Guinea pig/ Dunkin Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: <2% topical: 5%
MAIN STUDY	
Number of Animals	Test Group: 10 Control Group: 5
INDUCTION PHASE	Induction Concentration: intradermal injection 2% in water/ 2% in FCA:Water 1:1

Signs of Irritation	topical application 20% in vaseline Erythema (grades 2-4) occurred at injection sites for control and treatment injections. No signs of irritation after topical application.
CHALLENGE PHASE	
1 st challenge	topical application: 5% in vaseline
2 nd challenge	topical application:
Remarks – Method	Single challenge application

RESULTS

<i>Animal</i>	<i>Challenge Concentration</i>	<i>Number of Animals Showing Skin Reactions after: 1st challenge</i>	
		<i>24 h</i>	<i>48 h</i>
<i>Test Group</i>	5%	0	0
<i>Control Group</i>	5%	0	0

Remarks – Results	No skin reactions evident after the challenge exposure in experimental and control animals. No mortality occurred and no symptoms of systemic toxicity were observed. Yellow skin staining was seen during induction and challenge.
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CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
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TEST FACILITY	NOTOX B.V. (2000).
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7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
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METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/ Wistar Cr1: (WI) BR (outbred, SPF-quality)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 14 d
Vehicle	Water
RESULTS	No significant protocol deviations

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw/day</i>	<i>Mortality</i>
I (control)	5 males, 5 females	0	0/10
II (low dose)	5 males, 5 females	50	0/10
III (mid dose)	5 males, 5 females	200	0/10
IV (high dose)	5 males, 5 females	1000	0/10
V (control recovery)	5 males, 5 females	0	0/10
VI (high dose recovery)	5 males, 5 females	1000	0/10

Mortality and Time to Death

There were no mortalities in either sex at any dose level.

Clinical Observations

No clinical signs of toxicity or behavioural changes over the 28-day observation period. One male (50 mg/kg/day) showed hunched posture, piloerection and emaciation from day 9 onwards.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry: A decrease in aspartate aminotransferase (ASAT) activity was seen in group III and group IV males. Other statistically significant observations included increased chloride in groups II and III males, increased calcium in group III males and decreased triglycerides in group IV females.

After a 14-day recovery period, high dose animals showed small differences in sodium, calcium and inorganic phosphate compared with controls. These did not correlate to observations at the end of the treatment period.

Haematology: No findings.

Urinalysis: No urinalysis differences were noted between control and treated rats.

Effects in Organs

Organ weights of treated animals were considered to be similar to those of control animals. All macroscopic and microscopic observations were within the range of background pathology and occurred at similar incidences and severity in both control and treated rats.

Remarks – Results

Apart from the change in ASAT, all changes observed were minor, within historical controls and lacking dose relationship. Changes observed in recovery animals are small and do not correlate with effects observed at the end of the main study. Changes in ASAT were also small and were not corroborated by other findings.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on no treatment-related findings apart from discolouration effects being observed.

TEST FACILITY NOTOX B.V (1999o).

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Pre incubation procedure
Species/Strain *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2 uvrA.
Metabolic Activation System Uninduced hamster liver microsomal fraction (S9)
Concentration Range in Main Test a) With metabolic activation: 3-3330 µg/plate.
b) Without metabolic activation: 3-3330 µg/plate.
Vehicle DMSO, test substance prepared as a suspension
Remarks – Method The notified chemical precipitated on plates at test substance concentrations of 333 µg/plate and above. The concentration of 5000 µg/plate showed very heavy precipitate on plates, which would interfere with the scoring. Two independent tests were performed in triplicate. The second test used a maximum concentration of 333 µg/plate, chosen based on solubility.

RESULTS

Remarks – Results No cytotoxicity was observed but precipitation at and above 333 µg/plate obscured the background lawn. No significant increases in the numbers of revertant colonies either in the presence or absence of metabolic activation. Positive controls were used and in all cases resulted in large increases in revertants, confirming the sensitivity of the test system.

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions

of the test.

TEST FACILITY NOTOX B.V (1999p).

7.9. Genotoxicity – in vitro (Chromosomal aberration)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
EC Directive 92/69/EEC B.10 In vitro Mammalian Cytogenetic test

Species/Strain Human, 3 male donors

Cell Type/Cell Line Cultured human peripheral lymphocytes

Metabolic Activation S9 fraction from Aroclor 1254-induced rat liver

System

Vehicle DMSO

Remarks – Method A dose range finding test and two independent cytogenetic assays were conducted. The second cytogenetic assay dose levels were selected based on the inhibition of cell growth of the dose range finding test and the first cytogenetic assay.

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL)</i>	<i>Exposure Period</i>	<i>Harvest Time</i>
<i>Present</i>			
Test 1	1, 3 and 10	3h	24h
Test 2	1, 3 and 10	3h	48h
<i>Absent</i>			
Test 1	1, 3 and 10	3h	24h
Test 2	1, 3 and 10	24h	24h

All cultures selected for metaphase analysis.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/mL) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Present</i>				
Test 1	>10	>10	10	>10
Test 2		>10	10	>10
<i>Absent</i>				
Test 1	>10	>10	10	>10
Test 2		>10	10	>10

Remarks – Results No significant cytotoxicity was observed. Both in the absence and presence of S9-mix, the notified chemical did not induce a statistically or biologically significant increase in the number of cells with chromosome aberrations. Positive controls used in all cases resulted in large increases in chromosome aberrations, confirming the sensitivity of the test system.

CONCLUSION The notified chemical was not clastogenic to human peripheral lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY NOTOX B.V (1999q).

7.10. Genotoxicity – in vivo

No test report was provided.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO ₂ Evolution Test (Modified Sturm Test) with NOTIFIED CHEMICAL.
Inoculum	Activated sludge from municipal sewage treatment plant.
Exposure Period	28 days
Auxiliary Solvent	Not applicable
Analytical Monitoring	No analytical method available.
Remarks – Method	The test substance was quantitatively added to the test media and continuously stirred during the test. The concentrations of test substance and reference (sodium acetate) for testing were 44.6 mg/L. Test temperature: 21 ± 1 °C, pH variation 7.6-8.2.
	A temporary breakdown in aeration occurred on day 13 (<1 day). The breakdown was considered to have no effect on the outcome of the study.

RESULTS

<i>Test substance</i>		<i>Sodium acetate</i>	
<i>Day</i>	<i>% degradation</i>	<i>Day</i>	<i>% degradation</i>
2	0	2	12.5
14	0-1.9	14	73.3
29	6.6-8.6	29	86.3

Remarks – Results	Very little biodegradation was observed for the test substance with a maximum of 8.6% observed after 29 days. All criteria for acceptability of the test were met.
CONCLUSION	The notified chemical cannot be classed as readily biodegradable.
TEST FACILITY	NOTOX B.V (1999r)

8.1.2. Bioaccumulation

No bioaccumulation studies have been carried out.

The bioaccumulation potential of the substance in sediment/ soil is low as the log Pow, < -1.5 is low. While the substance has low water solubility (<20 µg/L) and it also has low solubility in n-octanol (<40 µg/L), therefore it is not expected to partition into lipids.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test (Static). EC Directive 92/69/EEC C.1 Acute Toxicity for Fish (Static)
Species	Carp (<i>Cyprinus carpio</i> , <i>Teleostei</i> , <i>Cyprinidae</i>)
Exposure Period	96 h
Auxiliary Solvent	Not applicable
Water Hardness	250 mg CaCO ₃ /L

Analytical Monitoring
Remarks – Method

Not done as no analytical method available
The test substance was not soluble in test medium or in the solvents DMSO, acetone and ethanol. Two test preparations were prepared for a limit test – a filtered (ca. 5 µm) and unfiltered solution prepared in the test medium at a nominal 100 mg/L without the use of an additive. Prior to testing, the medium was exposed for 3 days to 100 mg/L under continuous stirring to ensure maximum saturation was reached.. Filtration of one preparation through a large paper filter then removed the major part of the test substance (>ca. 5 µm). However, this was still turbid. Test temperature: 20 ± 1°C. pH range 7.5–8.0. Dissolved oxygen 7.7–9.3 mg/L.

RESULTS

Concentration mg/L		Number of Fish	Mortality				
Nominal	Actual		1 h	24 h	48 h	72 h	96 h
Control		7	0	0	0	0	0
100 filtered		7	0	0	0	0	0
100 non-filtered		7	0	0	0	0	0

LC₅₀
NOEC (or LOEC)
Remarks – Results

Not able to be determined
Not able to be determined
The substance induced no effects in carp exposed to a filtered or an unfiltered solution prepared at a nominal 100 mg/L. Owing to the extremely low solubility of the test substance in water (<20 µg/L), concentration levels toxic to carp could not be reached. With regard to the nominal concentration, the LC₅₀ of the substance was above 100 mg/L. It was noted that scoring of effects on the swimming behaviour and observations for possible precipitation were not possible during the course of the study owing to the yellow colour and the turbidity of the dispersions. At the end of the test period no visible effects were observed. Furthermore, both solutions appeared to have remained at least partly homogeneous during the study period.

CONCLUSION

The notified chemical is not toxic to Carp up to the limit of its solubility.

TEST FACILITY

NOTOX B.V (1999s)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 202 Daphnia sp. Acute Immobilisation Test (Static)
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – (Static)

Species
Exposure Period
Auxiliary Solvent
Water Hardness
Analytical Monitoring
Remarks – Method

Daphnia magna
48 hours
Not applicable
250 mg CaCO₃/L
Not done as no analytical method available
The test substance was not soluble in test medium or in the solvents DMSO, acetone and ethanol. Two test preparations were prepared for a limit test – a filtered (ca. 5 µm) and unfiltered solution prepared in the test medium at a nominal 100 mg/L without the use of an additive. Prior to testing, the medium was exposed for 3 days to 100 mg/L under continuous stirring to ensure maximum saturation was reached. Filtration of one preparation through a large paper filter then removed the major part of the test substance (>ca. 5 µm). However, this was still turbid. Test temperature: 20.5–20.8° C. pH range 7.7–8.0. Dissolved oxygen 7.7–9.3

mg/L.

RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h [acute]	48 h [acute]
Control		20	0	0
100 filtered		20		0
100 not filtered		20		0

LC₅₀
 NOEC (or LOEC)
 Remarks – Results

Not able to be determined
 Not able to be determined
 The substance induced no effects in *Daphnia magna* exposed to a filtered or an unfiltered solution prepared at a nominal 100 mg/L. Owing to the extremely low solubility of the test substance in water (<20 µg/L), concentration levels toxic for crustaceans could not be reached. With regard to the nominal concentration, the EC50 of the substance was above 100 mg/L. No immobility of daphnia was observed in both the filtered and unfiltered solutions. The 100 mg/L test solutions were turbid and yellow coloured. Consequently, scoring for immobility was impossible after 24 hours of exposure. However, owing to the observed precipitation and deposition of the test substance, scoring for immobility was no problem at the end of the 48-hour test period.

CONCLUSION

The notified chemical is not toxic to *Daphnia magna* up to the limits of its solubility.

TEST FACILITY

NOTOX B.V (1999t)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 201 Alga, Growth Inhibition Test.
 EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Selenastrum capricornutum, strain: CCAP 278/4

Species
 Exposure Period
 Concentration Range
 Nominal

72 hours
 0.1-100% of filtrate prepared at 100 mg/L

Concentration Range
 Actual

Not determined

Auxiliary Solvent
 Water Hardness

Not applicable
 24 mg CaCO₃/L

Analytical Monitoring

No analytical method available

Remarks – Method

The test substance was not soluble in test medium or in the solvents DMSO, acetone and ethanol. A stock solution for tests was prepared in the test medium at a nominal 100 mg/L without the use of an additive. The solution was stirred for ca. 93 hours then filtered through a paper filter to remove the major part of the test substance (>ca. 5 µm). The lower test concentrations were prepared by subsequent dilution of this stock.

A direct exposure test was conducted using the filtrate and dilutions and an additional test of indirect exposure of algal suspensions was also conducted to examine if the growth of algae would be indirectly affected due to the colour of the test solutions.

Test temperature: 20.5–20.8°C. pH range 7.7–8.0. Dissolved oxygen 7.7–

9.3 mg/L.

RESULTS

Remarks – Results	Not able to be determined. Filtrate prepared at 100 mg/L induced approximately 30% inhibition of total algal growth and reduced the growth rate slightly.
CONCLUSION	Under the conditions of the study, the test substance affected cell growth of the fresh water algal species by absorption of wavelengths necessary for algal growth instead of by toxic processes in a filtrate prepared at a nominal concentration of 100 mg/L. As a consequence, the EC50 value exceeded the solubility limit and any effects induced on algal cell growth are likely to be solely related to the indirect effect of light absorption by the dyeing properties of the test substance.
TEST FACILITY	NOTOX B.V (1999u)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.
Inoculum	Activated sludge from municipal sewage treatment plant.
Exposure Period	3 hours
Concentration Range	0.1-10 g/L
Nominal	
Remarks – Method	The test substance was hardly soluble in water and a weighed amount of the substance was added quantitatively to the test media.
RESULTS	
IC50	>10 g/L
NOEC	10 g/L
Remarks – Results	No significant inhibition in respiration rate of the sludge was recorded at any of the concentrations tested. By contrast reference material (3,5-dichlorophenol) had an EC50 of 6 mg/L indicating that the test was valid.
CONCLUSION	Under the conditions of the study, the test substance was not toxic to waste water (activated sludge) bacteria at concentrations up to and including 10 g/L. Hence, the EC50 exceeded 10 g/L.
TEST FACILITY	NOTOX B.V (1999v)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Up to 67% of the paint containing the notified chemical will be applied to various surfaces in industrial applications and the remaining 33% will be used as paint for domestic purposes on various surfaces. Almost no environmental exposure is expected at end use once the coating has dried to form a hard and durable paint matrix. The notified chemical in paints is fully encapsulated in the coatings matrix and as such is not likely to be released to the environment.

Up to 1650 kg of waste may be generated during coating application by industrial users each

year as a result of overspray. The majority of this waste will be sent to landfills for disposal. In landfill, the notified chemical in solid wastes is expected to be immobile, and eventually will degrade through biotic and abiotic processes, and consequently, should not pose a significant exposure hazard to the environment.

Almost no aquatic exposure is anticipated during normal usage of the coatings, there is a potential for aquatic exposure during accidental spills or from liquid wastes arising from clean up operations, although these will be in a highly diluted form and the chemical is expected to bind to sediments and be retained in sewage sludge.

A small amount of residual chemical (up to 66 kg per annum) will be disposed of through effluent from clean up operations or to landfill. Spills of notified chemical to land are expected to bind to soil and are not expected to be mobile or affect groundwater due to very low water solubility. Spills of notified chemical to waters are not expected to dissolve, and may settle to sediment due to the lack of water solubility. It is possible to calculate a predicted environmental concentration (PEC) based on the amount released to the sewer.

$$\begin{aligned}\text{PEC} &= V / P \times W \times D \\ &= 66 \times 10^6 / 20 \times 10^6 \times 200 \times 365 \\ &= 4.5 \times 10^{-5} \text{ mg/L}\end{aligned}$$

V=volume of chemical released (mg); P=population; W=water used/person/day (L); D=days/year.

The majority of the notified chemical will be incorporated into coatings and is expected to remain bound within cured coatings at low levels on metal substrates or both interior and exterior architectural surfaces. Once the chemical is within a cured coating it is likely to share the fate of the substrate, which may involve recycling or landfill at the end of its useful lifetime. For decorative use such substrates are expected to have a life span 10-50 years plus. Redecorating or demolition could release the notified chemical to the environment due to incineration or landfill.

9.1.2. Environment – effects assessment

The notified chemical is practically non-toxic to fish, daphnia, algae and sewage microorganisms up to the limit of its water solubility. The PNEC is calculated by taking the EC50 value and dividing this value by an assessment safety factor of 100 (OECD) for minimal algae/daphnia/fish acute toxicity endpoints. This gave a PNEC value of >1 mg/L since the EC50 was >100 mg/L nominal for the three trophic levels.

9.1.3. Environment – risk characterisation

A low potential for environmental release of the notified chemical is expected, with most wastes generated being either recycled, incinerated or landfilled. Within the landfill environment, the notified chemical is likely to degrade over time to simpler compounds of carbon. There will be limited release to the aquatic environment and an approximate PEC can be calculated for comparison with the PNEC. The PEC/PNEC ratio ($<4.5 \times 10^{-5}/1$) is much less than 1 indicating a low risk to the aquatic compartment. In conclusion the risk is expected to be low if the chemical is used in the manner and levels indicated by the notifier.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

During transport and storage, workers are unlikely to be exposed to the notified chemical unless packaging is breached. In the event of an accident, spills will be removed in accord with the MSDS and government regulations.

The main potential for occupational exposure is during blending operation leading to the preparation of end use products at the manufacturing facilities. Minimal exposure is expected at

this stage, as blending/package operations will be closed systems except for QC testing.

Inhalation exposure to the pigment powder during weighing and mixing is also possible. The notifier has stated that, at a workplace in Germany, exposure measurements of an azo pigment powder, manufactured and handled in the same way as the notified chemical, indicated low exposure levels (3-10% of the general limit values for respirable dust established in the German Technical Rules for Hazardous Substances). The MSDS for Hostaperm Yellow H5G contains recommendations for respiratory protection when handling large quantities of the product.

The possibility of exposure to drips and spills exists during the processes of preparation, cleaning, equipment maintenance and during product changeover. Dermal exposure would be the predominant route of occupational exposure to workers during these activities. Workers handling connections or equipment will be properly protected with PPE as recommended in the MSDS.

Exposure can also occur during industrial application (spraying) of the finished products. However, exposure will be minimal as these operations are either carried out in closed systems, workers are well equipped with gas masks or the direction of the strong ventilation prevents any contact of workers with the contaminated air. Furthermore, the notified chemical will be present at a low concentration in finished product at this stage.

Exposure can occur for professional printers using architectural coatings containing the notified chemical, and exposure is expected to be similar to that for members of the public discussed below, although exposure is expected to be more regular.

9.2.2. Public health – exposure assessment

Paints containing the notified chemical will be used by the general public as well as professional painters. It is estimated that the notified chemical will be present in paint formulations at a maximum level of <10%. The notified chemical will be blended with resins and other components of the paint formulations. As a component bound in the resin substrate, routine exposure of the general public is expected to be minimal. The most probable public exposure will occur by dermal contact through the use of paints containing the notified chemical. However, such exposure would be limited to one or two occasions per year, and probably one or two days for each occasion. As the notified chemical is bound to the resin substrate and present at a concentration of <10% in the paint, exposure of public to the notified chemical would be expected to be minimal as a result of contact with painted material.

During the transport and handling of the notified chemical, the public will only be exposed if there is an accident resulting in spillage. Therefore, the overall public exposure to the notified chemical will be low.

9.2.3. Human health - effects assessment

The notified chemical was shown to be of low acute toxicity via the oral and dermal routes in rats. It was not a skin or eye irritant nor a skin sensitiser.

The notified chemical was not mutagenic in bacteria, and was not clastogenic in cultured human peripheral lymphocytes. In a 28-day oral repeat dose study, the NOAEL was >1000 mg/kg/day. No information on inhalation toxicity was provided, but the low solubility of the notified chemical in water or lipid and its low oral toxicity indicate that it is probable the inhalation toxicity is not high.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

9.2.4. Occupational health and safety – risk characterisation

The main occupational exposure to the notified chemical is expected during the blending operations leading to the preparation of end use products at the customer manufacturing facilities. However, for these workers, the risk of exposure is expected to be low, as blending/packaging operations will be closed systems except for QC testing. While the effects of inhalation exposure are not known, inhalation exposure to the pigment powder during these tasks will be low with suitable respiratory protection recommended in the MSDS. Inhalation risk is negligible after the pigment has been incorporated in paint.

The opportunity for skin exposure exists during product changeover and equipment maintenance. In these cases, workers handling connections or equipment will be properly protected with PPE as recommended in the MSDS. At the paint formulation sites, the point at which the container is opened and connected to the blending vessels would be under the control of exhaust ventilation to deal with the hazards associated with other ingredients such as pigments and solvents. Eye contact is only likely in the case of accidental splashes and is controlled by the use of safety glasses or goggles.

End use of the paint in domestic and industrial situations (spraying) of the finished products may potentially result in frequent exposure. However, exposure will be minimal as these operations are either carried out in closed systems, workers are well equipped with gas masks, or the direction of the strong ventilation prevents any contact of workers with the contaminated air. The risk of adverse health effects from the notified chemical is low given that it is present at a low concentration in the finished product and is not a hazardous substance.

Worker exposure during transport, storage and distribution of the notified chemical and its products is unlikely, except in the event of an accidental spill. Exposure after a spill should be controlled by the recommended practices for cleaning up of spills stated in the MSDS.

Overall, the occupational risk is low for handlers of the notified chemical, as the notified chemical is expected to have low hazard at the concentration used. The occupational risk would be further reduced due to the use of enclosed systems for blending/packaging, and the wearing of protective clothing during product changeover and equipment maintenance.

9.2.5. Public health – risk characterisation

The public will be mainly exposed to the notified chemical in do-it-yourself paint products and through exposure to cured industrial and architectural coatings. The notified chemical is expected to have low hazard at the low concentration used in finished products. Furthermore, exposure of the general public to the notified chemical as a result of its transport or through its use is assessed as being low. Therefore, the risk to the public resulting from the use of the notified chemical is expected to be very low.

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

10.1. Hazard classification

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

As a comparison only, the classification of [notified chemical](#) using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

Symbol: Environment
Signal Word: No signal word
For environment: Chronic Category 4

10.2. Environmental risk assessment

The notified chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

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

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES **Occupational Health and Safety**

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical in the pigment powder form:
 - Exhaust ventilation when weighing and adding the pigment,
 - Enclosed system for blending
- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical in formulated paints:
 - Exhaust ventilation when opening and connecting the drums,
 - Enclosed system for blending/packaging,
 - Enclosed spray paint application system for industrial use.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in the pigment powder form:
 - Protective gloves,
 - safety glasses or goggles
 - where engineering controls and work practices do not reduce particulate exposure to safe levels, an air fed respirator should also be used
 - industrial clothing

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in formulated paint:
 - Protective gloves,
 - safety glasses or goggles
 - industrial clothing

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

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- The following control measures should be implemented by end users to minimise environmental exposure during use of the notified chemical:
 - Do not allow material or contaminated packaging to enter drains, sewers or water courses.

Disposal

- Wastes generated during industrial application should be disposed of through a licensed waste contractor. Wastes generated during domestic use should be disposed of according to the following instructions: “Do not pour leftover paint down the drain. Unwanted paint should be brushed out on newspaper, allowed to dry and then disposed of via domestic waste collections. Empty paint containers should be left open in a well-ventilated area to dry out. When dry, recycle steel containers via steel can recycling programs. Disposal of empty paint containers via domestic recycling programs may differ between local authorities. Check with your local council first.”

Emergency procedures

- Spills/release of the notified chemical should be taken up with adsorbent material and collected in a tight closed container for disposal by licensed waster contractors in accordance with local authorities.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - **Uses are** proposed leading to greater quantities of the notified chemical released to water better defined test results for the partition coefficient and adsorption/desorption will be required

or

- (2) Under Section 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

13. BIBLIOGRAPHY

- NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (2002) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2002)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOTOX B.V (1999a). Determination of the Melting Temperature of the Notified Chemical. Project Number: 246228, 2 July 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999b). Determination of Density of the Notified Chemical. Project Number: 246241, 2 July 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999c). Calculation of the Vapour Pressure of the Notified Chemical. Project Number: 263227, 16 June 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999d). Determination of the Water Solubility of the Notified Chemical. Project Number: 246274, 16 June 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999e). Determination of the Partition Coefficient (n-octanol/water) of the Notified Chemical. Project Number: 246285, 16 June 1999). 's-Hertogenbosch, Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999f). Determination of the Particle Size Distribution of the Notified Chemical. Project Number: 246353, 02 July 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999g). Determination of the Flammability of the Notified Chemical. Project Number: 246296, 02 July 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999h). Determination of the Relative Self-Ignition Temperature of the Notified Chemical. Project Number: 246331, 2 July 1999). 's-Hertogenbosch, Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999i). Statement on the Explosive Properties of the Notified Chemical. Project Number: 246329, 02 July 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999j). Statement on the Oxidizing Properties of the Notified Chemical. Project Number: 246342, 02 July 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999k). Assessment of Acute Oral Toxicity with the Notified Chemical. Project Number: 246364, 19 June 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999l). Assessment of Acute Dermal Toxicity with the Notified Chemical. Project Number: 246375, 19 June 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999m). Primary Skin Irritation/Corrosion Study with the Notified Chemical. Project Number: 246386, 19 June 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999n). Acute Eye Irritation/Corrosion Study with the Notified Chemical. Project Number: 246397, 19 June 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).

- NOTOX B.V (1999o). Subacute 28-day Oral Toxicity with the Notified Chemical by Daily Gavage in the Rat, Followed by a 14-day Recovery Period. Project Number: 246421, 20 June 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999p). Evaluation of the Mutagenic Activity of the AZO Pigment (Notified Chemical) in the Salmonella Typhimurium reverse Mutation Assay and the Escherichia Coli reverse Mutation Assay. Project Number: 246432, 01 February 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999q). Evaluation of the Ability of the Notified Chemical to Induce Chromosome Aberrations in Cultured Peripheral Human Lymphocytes. Project Number: 246443, 31 March 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999r). Determination of 'Ready' Biodegradability: Carbon dioxide (CO₂) Evolution Test (Modified Sturm Test) with the Notified Chemical. Project Number: 246454, 26 April 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999s). 96 hour Acute Toxicity Study in Carp with the Notified Chemical (Static) (Project Number: 246465, 26 April 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999t). Acute Toxicity Study in *Daphnia Magna* with the Notified Chemical (Static) (Project Number: 246476, 26 April 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999u). Fresh Water Algal Growth Inhibition Test with the Notified Chemical (direct and indirect exposure) (Project Number: 246487, 26 April 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (1999v). Activated Sludge Respiration Inhibition Test with the Notified Chemical. Project Number: 246498, 26 April 1999). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- NOTOX B.V (2000). Assessment of Contact Hypersensitivity to the Notified Chemical in the Albino Guinea Pig. Project Number: 279258, 7 February 2000). 's-Hertogenbosch, The Netherlands, Notox B.V (Unpublished data submitted by Clariant).
- United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.