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

FULL PUBLIC REPORT

Pigment Additive FGR

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Director

Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT	4
1. APPLICANT AND NOTIFICATION DETAILS	4
2. IDENTITY OF CHEMICAL	4
3. COMPOSITION.....	4
4. INTRODUCTION AND USE INFORMATION	4
5. PROCESS AND RELEASE INFORMATION.....	5
5.1. Distribution, Transport and Storage.....	5
5.2. Operation Description.....	5
5.3. Occupational Exposure	5
5.4. Release.....	6
5.5. Disposal	7
5.6. Public exposure	7
6. PHYSICAL AND CHEMICAL PROPERTIES.....	7
7. TOXICOLOGICAL INVESTIGATIONS	11
7.1. Acute toxicity – oral	11
7.2. Irritation – skin.....	11
7.3. Irritation - eye.....	12
7.4. Skin sensitisation.....	14
7.5. Repeat dose toxicity.....	14
7.6. Genotoxicity - bacteria.....	15
7.7. Skin and Mucous Membrane Tolerance.....	15
8. ENVIRONMENT.....	16
8.1. Environmental fate	16
8.2. Ecotoxicological investigations.....	16
9. RISK ASSESSMENT	16
9.1. Environment.....	16
9.1.1. Environment – exposure assessment.....	16
9.1.2. Environment – effects assessment.....	17
9.1.3. Environment – risk characterisation.....	17
9.2. Human health	17
9.2.1. Occupational health and safety – exposure assessment.....	17
9.2.2. Public health – exposure assessment.....	18
9.2.3. Human health - effects assessment.....	18
9.2.4. Occupational health and safety – risk characterisation.....	18
9.2.5. Public health – risk characterisation.....	19
10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS	19
10.1. Hazard classification.....	19
10.2. Environmental risk assessment.....	19
10.3. Human health risk assessment.....	19
10.3.1. Occupational health and safety.....	19
10.3.2. Public health.....	19
11. MATERIAL SAFETY DATA SHEET	19
11.1. Material Safety Data Sheet.....	19
11.2. Label	20
12. RECOMMENDATIONS.....	20
12.1. Secondary notification	22
13. BIBLIOGRAPHY	22

FULL PUBLIC REPORT

Pigment Additive FGR

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Clariant (Australia) Pty Ltd (ABN 30 069 435 552)

675 Warrigal Road

Chadstone VIC 3148

NOTIFICATION CATEGORY

Limited-small volume: Chemical other than polymer, (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Identity of chemical

Composition

Exact import volume and

Specific use

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

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

Hydrolysis as a function of pH

Partition coefficient;

Absorption/Desorption; and

Particle size

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (PMN 92-1449)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)

Pigment Additive FGR

MARKETING NAME(S)

Permanent Red FGR 02

3. COMPOSITION

DEGREE OF PURITY

The notified chemical is not available as a pure substance.

4. INTRODUCTION AND USE INFORMATION

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

The notified chemical will be imported into Australia as a component of Permanent Red FGR 02 at <5% concentration. The imported solid pigment product will be used in the formulation of various paint tinter formulations and subsequently added to form tinted paint products, such as decorative

paints.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	<1	<1	<1	<1	<1

USE

Ingredient in colourants for decorative paints.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY

Melbourne, Sydney, Brisbane

IDENTITY OF MANUFACTURER/RECIPIENTS

Clariant (Australia) Pty Ltd

675 Warrigal Road

Chadstone Vic 3148

TRANSPORTATION AND PACKAGING

The imported solid pigment products will be packaged, stored and transported in 25 kg multi-layer paper sacks inside fibreboard cartons.

The pigment products will be transported by road to contract stores for subsequent distribution to customers as required.

Formulated paint tinter will be packed in 1 or 20L paint cans. The finished paints will be packaged into 1, 2, 4, 10 or 20L containers

5.2. Operation Description

The notified chemical will not be manufactured in Australia. The imported pigment product will be used in the manufacture of various ranges of paint tinter products. Paint tinter production involves routine weighing, blending, milling and filling operations. Preparation of paints will be conducted at retail outlets or by professional painters prior to application.

5.3. Occupational Exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Warehouse/ Distribution	6	<1 hour per day	25 days per year
Process workers – manufacture/ packaging	20	Up to 2 hours per day	55 days per year
Quality control	8	<1 hour per day	55 days per year
Technical Service/ Development Chemists	8	<1 hour per day	10 days per year
Sales persons (Retail paint outlets)	3000	15 minutes per day	250 days per year
Professional painters	>1000	Up to 6 hours per day	200 days per year

Exposure Details

Warehousing and distribution of the notified chemical involves moving and storing of packaged pigment products (containing <5% notified chemical) and packaged tinter products (containing <0.5% notified chemical).

Process workers will be involved in retrieval of pigment from stores, weighing and addition of the pigment to paint batches, supervision of blending and bead milling operations for paint tinter

production and supervision of automatic filling of tinters into 1 or 20L cans. Weighing and transfer of raw materials, including pigments, to the mixing vessels are carried out under a mechanical ventilation system that creates a flow of air away from operators. Mixing and blending of tinter components takes place in closed mixing vessels.

Paint tinter manufacture and packaging operators wear protective gloves, eye protection long-sleeved industrial clothing and safety boots when handling pigment products and supervising paint manufacture.

Quality control personnel will collect samples (approximately 500 g) of paint tinter batches to evaluate performance characteristics of the batches. Tinter batches will include the notified chemical diluted with other paint components. Technical service and development chemists will be involved in laboratory development of tinter formulations with possible follow up laboratory trials to investigate performance characteristics of the formulations. These workers are required to wear laboratory coats, safety glasses/goggles, protective gloves and safety boots as appropriate to the particular tasks.

Paint preparation will be conducted primarily at paint store outlets. Sales personnel at paint store outlets will handle packaged tinter products, and fill and clean the dispenser tube on volumetric dispensing machines that dispense the paint tinter into paint bases.

Professional painters who may also mix their own paint, will be exposed to the finished paint products during brush and roller application and to the dry painted surfaces in which the notified chemical is bound within the paint polymer system. Paint products will contain <0.05% notified chemical.

5.4. Release

RELEASE OF CHEMICAL AT SITE

None of the reformulation operations will be controlled by the notifier. It is likely there will be more than 1 paint tinter manufacturer, each with an operational period of up to 100 days during which the notified chemical will be used.

Release of the notified chemical during weighing, blending, milling and filling operations will only be minor as in most cases spills at these stages of operation can be reclaimed. It is estimated that the release of pigment over the operational period would equate to an annual loss of 0.36 kg of the notified chemical at each site. These losses would be washed into on-site waste water systems.

Production loss of paint tinter formulations due to cleaning operations at each manufacturing site would amount to up to 2.25 kg of notified chemical per annum at each site.

Thus the total amount of notified chemical being lost to the waste water system at each site would be equivalent to approximately 2.6 kg per annum.

It is estimated that a maximum of 2 kg of the notified chemical per year would be disposed of in packaging through a licensed waste disposal contractor.

In the ventilation system there will be filters which catch any dust generated during the paint tinter production process. It is estimated that the amount of notified chemical collected in this manner will be approximately 1 kg/annum. This collected material will be disposed of to landfill with other solid wastes.

RELEASE OF CHEMICAL FROM USE

Paint Retail Stores

It is estimated that over 1500 retail paint store outlets throughout Australia are likely to use the tinter products for tinting water based emulsion paints and alkyd or oil based paints.

Up to 30 kg of the notified chemical will be lost from paint tinter remaining in paint cans across the retail outlets. Cans retaining the residual paint tinter formulation will most likely be sent to authorised landfill sites.

The dust collected in the filters of the ventilation system will be disposed of to landfill with empty packaging and other solid wastes generated during the paint tinter production process.

Paint Application:

The volume of paint containing the notified chemical 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 a total of up to 10 kg of the notified chemical will remain as part of the paint residue in the emptied cans. As the paint residual in the empty tin cures, the notified chemical will become bound in the hardened paint film.

Brushes, rollers and paint trays used for painting with the 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 equates to a total loss of approximately 20 kg per year of the notified chemical, much of which will be flushed to the sewer.

5.5. Disposal

All of the notified chemical will be incorporated into paint tinter products. Any contaminated spilt material will either be washed into the onsite wastewater treatment plant or collected with absorbent material and then placed in a container ready for disposal to landfill.

Solid waste from the paint tinter manufacturing process that cannot be reused in production, including dust collected from in the ventilation filters and empty import containers with any residual pigment, will be disposed of at approved landfill sites.

The wastewater containing the notified chemical is treated through the on-site chemical water treatment plants before release to sewer. Residue solids from the water treatment plant are eventually removed to authorised landfill sites.

All of the final paint products containing the notified chemical will be used for decorative or architectural purposes. Liquid wastes arising from cleaning operations of paint application tools (eg brushes etc) are expected to be discharged to the sewer in a highly diluted form or spread over soil in domestic locations, across Australia. 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.

The ultimate release to the environment of the notified chemical will be the fate of the substrate to which the paint has been applied. Such substrates are expected to have a lifespan of 10-50 years. Redecorating or demolition could release the notified chemical to the environment due to incineration or landfill.

5.6. Public exposure

Any routine exposure of the general public to the notified chemical will be as a minor component of decorative paint products either during DIY domestic application of paints or as a component of cured paints.

The potential for exposure of the public to the notified chemical during normal industrial storage, handling and transportation is minimal. The pigment products will be packaged in multi-layer paper sacks in cartons. This packaging 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 pigment product being released from the packaging for exposure to the public or for contamination of the environment.

6. PHYSICAL AND CHEMICAL PROPERTIES

The physico-chemical properties tabulated below are for a pigment product containing <5% notified chemical, unless otherwise stated.

Appearance at 20°C and 101.3 kPa

Red powder

Melting Point/Freezing Point

Decomposes at 270°C

Remarks

Test report not provided

Density	1300 kg/m ³
Remarks	Test report not provided
Vapour Pressure	Not determined
Remarks	The notified chemical is solid. It is expected that the vapour pressure would be low due to the molecular weight being greater than 500.
Water Solubility	insoluble (below detection limit, < 0.02 mg/L) at 20°C
METHOD	Clariant GmbH standard method.
Remarks	No study report was provided for the notified chemical, but the standard method used was submitted.
	Analytical Method: Spectrophotometry
	Five (5) mg of pigment is dispersed in 30 mL of bidistilled water and shaken for 7 hours at 80°C initially, then for 16, 40 and 64 hours at 25°C. The solution is then filtered and an aliquot of the filtrate is sampled in a spectrophotometer (700-300 nm). The Lambert-Beer equation is used to determine the solubility.
Hydrolysis as a Function of pH	Not determined.
Remarks	The notified chemical does not contain any groups that would readily undergo hydrolysis in the environmental pH range 4-9.
Partition Coefficient (n-octanol/water)	Not determined.
Remarks	Since the notified chemical is water insoluble this study could not be undertaken. It is expected that the partition coefficient would be high, thus indicating the chemical would partition to organic matter, sediments and soils.
Adsorption/Desorption	Not determined.
Remarks	It would be expected that the chemical would adsorb to, or become associated with soil or sediments.
Dissociation Constant	Not determined.
Remarks	The notified chemical does not contain structural elements that are capable of dissociation.
Particle Size	No data available
Remarks	The notified chemical cannot be isolated in pure form. However, the particle size of the imported pigment product is expected to be at least in the respirable range (<180µm).
Flash Point	Not determined
Remarks	The notified chemical is solid.
Flammability Limits	Combustible. When exposed to flame, the product exhibits short flaring up without spreading.
Remarks	Test report not provided.
Autoignition Temperature	190 - 200°C
Remarks	Test report not provided.

Explosive Properties

The notified chemical does not have explosive properties.
However, solid organic substances have the potential to cause dust explosions.

Thermal stability of product containing <5% notified chemical is >270°C (-130J/g).

Minimum ignition energy of product containing <5% notified chemical is 100-300 mJ

Remarks Test report not provided.

Reactivity

Not determined

Remarks The notified chemical is stable under normal conditions of use.

7. TOXICOLOGICAL INVESTIGATIONS

The notified chemical, Pigment Additive FGR, cannot be isolated in pure form. Therefore, no toxicity studies have been carried out with the notified chemical alone. The following toxicity studies were either carried out with the commercial product Permanent Red FGR 02 (containing <5% Pigment Additive FGR) or Pigment Red 112 (not containing Pigment Additive FGR). It is proposed that Pigment Additive FGR will have a similar toxicological profile to that of Permanent Red FGR 02 and Pigment Red 112 based on the similarities in chemical structure.

<i>Endpoint</i>	<i>Assessment Conclusion</i>
Rat, acute oral	LD50>5000 mg/kg bw, low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - non-adjuvant test.	no evidence of sensitisation.
Rat, unknown route of exposure, repeat dose toxicity – 43 days.	No conclusion can be established because the test conditions employed are not sufficiently documented
Skin and Mucous membrane tolerance	non irritating
Genotoxicity - bacterial reverse mutation	non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Pigment Red 112 (0% notified chemical)
METHOD	Not specified
Species/Strain	Rat/Unspecified
Vehicle	Not specified
Remarks – Method	A study with Pigment Red 112 (not containing the notified chemical) was carried out in 1966. Test report was not submitted.
RESULTS	
LD50	>5000 mg/kg bw
Remarks - Results	One day after treatment, all animals (5/sex) recovered from clinical symptoms of poisoning. No macroscopic abnormality was seen at necropsy.
CONCLUSION	The test substance is of low toxicity via the oral route.

7.2. Irritation – skin

TEST SUBSTANCE	Permanent Red FGR 02 (containing <5% notified chemical)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White

Number of Animals	3/unknown
Vehicle	PEG 400
Observation Period	72 hours
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	1 hour	0
<i>Oedema</i>	0	0	0	1	1 hour	0

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

Remarks - Results	Light pink colouration was observed on the treated skin areas for up to 24 hours. The slight colouration did not inhibit proper evaluation of irritation effects.
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CONCLUSION	The test substance is slightly irritating.
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TEST FACILITY	Hoechst AG, Department of Toxicology (1983a)
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7.3. Irritation - eye

TEST SUBSTANCE	Permanent Red FGR 02 (containing <5% notified chemical)
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METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3/unknown
Observation Period	72 hours
Remarks - Method	Treated eyes were washed with physiological saline 24 hour after application of the test substance. The eyes were examined for corneal lesions using fluorescein solution 24 hours prior to the start of the test in one animal, and at 24 and 72 hours after application of the test substance in all animals.

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	0	0.3	1	24 hours	0
<i>Conjunctiva: chemosis</i>	0	0	0	0	0	0
<i>Conjunctiva: discharge</i>	0	0	0	0	0	0
<i>Corneal opacity</i>	0	0	0	0	0	0
<i>Iridial inflammation</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	Redness and red discharge from the conjunctiva was observed in all animals at 1-hour observation period, which were resolved within 24 hours.
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CONCLUSION	The notified chemical is slightly irritating to the eye.
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TEST FACILITY	Hoechst AG, Department of Toxicology (1983b)
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7.4. Skin sensitisation

TEST SUBSTANCE	Pigment Red 112 (0% notified chemical)
METHOD	OECD TG 406 Skin Sensitisation - Buehler test. EC Directive 96/54/EC B.6 Skin Sensitization - Buehler test. US EPA: OPPTS 870.2600 Skin Sensitisation
Species/Strain	Guinea pig/Moellegaard
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 20% in sesame oil
MAIN STUDY	
Number of Animals	Test Group: 20 females Control Group: 10 females
INDUCTION PHASE	Induction Concentration: topical application 20% in sesame oil
Signs of Irritation	No irritation was observed after each treatment at days 2, 9 and 16.
CHALLENGE PHASE	
1 st challenge	topical application: 20% in sesame oil
Remarks - Method	During the preliminary study, the topical application of 100% test substance tinted the skin red and erythema could not be scored. Treatment did not induce oedema. No irritation was observed after treatment of 4 and 20% test substance.

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>	20% in sesame oil	0/20	0/20
<i>Control Group</i>	sesame oil	0/10	0/10

Remarks - Results	No signs of irritation were observed during the induction phase. At 20% challenge concentration, all scores in both test and control animals were zero.
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CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.
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TEST FACILITY	Aventis Pharma Deutschland GmgH (2002)
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7.5. Repeat dose toxicity

TEST SUBSTANCE	Pigment preparation containing 50% Pigment Red 112, 0% notified chemical
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METHOD	Not specified
Species/Strain	Rat/unspecified
Route of Administration	Not specified
Exposure Information	Total exposure days: 43 days
Vehicle	Not specified

Remarks	A study with a liquid preparation containing 50% Pigment Red 112 (not containing the notified chemical) was carried out in 1958. No report is available for the study. No adverse effects were detected.
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CONCLUSION	
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The No Observed (Adverse) Effect Level (NO(A)EL) can not be established because the test conditions employed are inadequate or not sufficiently documented. Therefore, on the basis of inadequate evidence, no conclusion is made.

7.6. Genotoxicity - bacteria

TEST SUBSTANCE	Permanent Red FGR 02 (containing <5% notified chemical)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.14 Mutagenicity – Reverse Mutation Test using Bacteria. US EPA: 798.5265 The Salmonella typhimurium Reverse Mutation Assay Standard plate test and Prival modification pre incubation procedure TA1535, TA1537, TA98, TA100.
Species/Strain	Aroclor 1254 – induced rat liver S9 S9
Metabolic Activation System	a) With metabolic activation: 4 to 5000 µg/plate.
Concentration Range in Main Test	b) Without metabolic activation: 4 to 5000 µg/plate.
Vehicle	Dimethylsulfoxide (DMSO)
Remarks - Method	Two independent mutagenicity studies were conducted in the standard plate test (Ames test) and in modified preincubation test (Prival test). Prival test was conducted using pre-incubation with hamster S9 supplemented with flavine mononucleotide. A precise cytotoxicity experiment was conducted using histidine enriched agar plates and a dilution of TA100 in parallel with the second experiment.

RESULTS

<i>Metabolic Activation</i>	<i>Test Substance Concentration (µg/plate) Resulting in:</i>			
	<i>Cytotoxicity in Preliminary Test</i>	<i>Cytotoxicity in Main Test</i>	<i>Precipitation</i>	<i>Genotoxic Effect</i>
<i>Absent</i>				
Test 1 - Standard Plate Test	None	None	500 µg and above	None
<i>Present</i>				
Test 1 - Standard Plate Test	None	None	500 µg and above	None
Test 2 - Modified Pre-incubation Test	None	None	500 µg and above	None

Remarks - Results

Precipitation was evident at concentrations 500 µg/plate and above. Toxicity was therefore evaluated at 2500 µg/plate and lower doses.

In the standard plate incorporation assay, no significant increase in the number of revertant colonies in the presence or absence of S9.

In the modified preincubation test, the test substance did not cause a significant increase in the number of revertant colonies in the presence of hamster liver S9.

Appropriate positive controls induced marked increases in the number of revertant colonies, indicating that the test system responded appropriately.

CONCLUSION

The test substance was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

Hoechst AG, Pharma Development Corporate Toxicology (1996)

7.7. Skin and Mucous Membrane Tolerance

TEST SUBSTANCE	Permanent Red FGR 02 (containing <5% notified chemical)
METHOD	The test method was described to be a skin and mucous membrane tolerance test in accord with FDA regulations. The test method is similar to the OECD Acute Dermal and Eye Irritation/Corrosion.
Species/Strain	Rabbit/Himalayan White
Number of Animals	6
Vehicle	PEG 400
Observation Period	72 hours
Type of Dressing	Occlusive.
RESULTS	
Remarks – Results	No individual animal data are included in the study report. No irritation was observed on the treated skin but irritation to the mucous membrane was observed 1 hour after application.
CONCLUSION	The test substance was classified as not irritant to the skin and to mucous membrane under the conditions of the study.
TEST FACILITY	Hoechst AG, Pharma Research Toxicology (1979)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted. The notified chemical is unlikely to readily degrade in the environment or bioaccumulate due to its low aquatic exposure. Over time it will undergo abiotic and biotic biodegradation.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The majority the notified chemical will be incorporated with other paint components to form very high molecular weight and stable paint film that firmly adheres to the primer layer to which it is applied. The majority of waste generated during paint tinter production and use will go to landfill where it is unlikely to present a hazard to the environment, as it is not water soluble and thus will not be mobile. The notified polymer is likely to slowly degrade and become associated with the soil matrix and sediments.

During paint tinter production some of the notified chemical will enter the on-site effluent treatment plant, where it is likely to become associated with sludge. In a worst case basis, if none of the notified chemical is removed in the on-site treatment plants but is released to municipal sewer, then the following PEC can be calculated, assuming two production sites use the chemical within the Melbourne Water sewage system:

Amount of notified chemical released per site	2.6 kg
Number of production sites	2
Total amount of notified chemical in sewer	5.2 kg
Number of days during which notified chemical used	55 days
Population of Melbourne	3 million
Amount of water released per person to sewer	150 L
Predicted Environmental Concentration in effluent entering STP	<u>5200x1000x1000</u>

$$\frac{55 \times 150 \times 3000000}{365 \times 10^6} = 0.21 \mu\text{g/L}$$

This PEC is due solely to paint tinter production and does not take into account the fact that during treatment in the on-site effluent treatment plant and in the municipal STP the notified chemical will become associated with organic material, which will become part of the sludge. Therefore, the PEC in receiving waters will be much lower. The sludge will be removed on an as needed basis from the on-site plant and STP, allowed to dry and then disposed of to landfill or applied to land.

During use of the paint, some of the notified chemical will be disposed of to sewer by the general public due to cleaning of equipment and spills. A PEC for this disposal to sewer can be calculated as follows:

Amount of notified chemical released	20 kg
Number of days paint possibly used	365 days
Population of Australia	19 million
Amount of water released per person to sewer	150 L
Predicted Environmental Concentration in effluent in STP	$\frac{20000 \times 1000 \times 1000}{365 \times 150 \times 19000000}$
	=0.019 $\mu\text{g/L}$

This PEC is an order of magnitude lower than the PEC for paint tinter production, and is lower than the limit of detection used in the water solubility study. Release to sewer will be low and diffuse due to the low concentration of the chemical in paint and its use is spread across Australia, respectively. Any notified chemical in the sewer is likely to adhere to suspended organic material or sediments, thus the PEC in receiving waters would be much lower.

At the end of their useful lives, buildings to which the paint has been applied will also be disposed to landfill.

9.1.2. Environment – effects assessment

No ecotoxicity data were submitted. However, aquatic exposure is expected to be minimal during normal usage of the pigment/paint. Aquatic toxicity is also likely to be limited by low water solubility.

9.1.3. Environment – risk characterisation

The majority of the notified polymer will be incorporated at a low concentration level into architectural paints and, once applied and dried, poses little risk to the environment since an inert matrix will be formed.

Wastes will be mainly disposed of to landfill or it may be incinerated. In landfill, the notified chemical is expected to associate with soil and sediment and slowly degrade through biotic and abiotic processes to water and oxides of carbon and nitrogen. If wastes were incinerated then the notified chemical would be destroyed with the production of water vapour, and oxides of carbon and nitrogen.

With release to sewer (either accidental or intentional), due to its expected water insolubility, the notified chemical will become associated with sediment and degrade slowly through the abiotic and biotic processes.

The limited exposure of the notified chemical to the aquatic compartment indicates that it is unlikely to have an adverse effect on aquatic organisms.

The majority of the notified polymer will be applied to surfaces and either share the fate of the surface at the end of its useful life (most likely to landfill) or be removed by sanding. If removed by sanding the coating containing the notified polymer will be broken up into solid particulate matter and most likely disposed of to landfill or deposited on nearby ground.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical will be imported as a component of solid pigment products. Dermal, ocular and inhalation exposure may occur during certain operations in paint tinter manufacturing process. For example, inhalation of and ocular exposure to airborne particulates may occur when weighing and adding pigment to paint tinter batches. Dermal exposure to drips and spills is possible if paint containers are overfilled, and during maintenance and cleaning of mixing vessels.

Dermal exposure will be the main route of exposure for quality control and development chemists who may be exposed to the notified chemical during sampling and analysis of paint tinter batches.

Skin and eye contact is possible when sales personnel and professional painters add the tinter into paint prior to paint application. Skin contact is also possible when the final paint is applied by brush or roller application.

However, exposure to significant amounts of the notified chemical is limited because of the low concentration of the notified chemical present in the pigment products, paint tinters and final paints. The largely enclosed mixing, and automated filling operations, and the use of engineering controls are likely to minimise exposure when handling the notified chemical. In addition, weighing and adding of raw materials are conducted under a mechanical ventilation system in which flow air is drawn away from the operators.

9.2.2. Public health – exposure assessment

The paint will be available for use as DIY paints; therefore public exposure will be widespread. Dermal exposure may occur during paint application, as DIY painters are not likely to wear gloves while painting. In addition, members of the public may make dermal contact with various architectural surfaces coated with paints containing the notified chemical. However, public exposure is considered low given that the final paint contains low levels of the notified chemical and once dried, the notified chemical is likely to be bound within a cured paint film and will not be available for separate exposure.

Public exposure to the notified chemical during storage and transport is expected to be negligible.

9.2.3. Human health - effects assessment

There are no toxicological data available for the notified chemical since the chemical does not exist in a pure form. A limited number of toxicity studies were conducted on products either containing <5% notified chemical or of a substance structurally similar to the notified chemical. These studies have been provided and accepted as “read across data” for the assessment of the possible adverse health effects of the notified chemical.

By analogy, the notified chemical is not expected to differ substantially from that of the product containing <5% notified chemical or the substance structurally similar to the notified chemical.

The notified chemical is expected to have low acute oral toxicity. It may be slightly irritating to skin and eyes, but is not expected to be sensitising to skin. Upon repeated exposure, there were no adverse effects reported although the data available was regarded as inadequate for proper evaluation. The notified chemical is not expected to be genotoxic. On the basis of the data supplied, the notified chemical would not be classified as 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 notified chemical is never isolated in its pure form and therefore occupational exposure to the notified chemical would only occur from contact with the pigment products, paint tinters or final paints. Dermal exposure is the main route of exposure during paint manufacture and application. In addition, inhalation exposure to airborne particulate of the imported solid pigment product is of concern when weighing and adding the pigment product into a mixing vessel. The particle size of the pigment product was not provided. However, products of this type are usually

at least in the insipid range. The notified chemical is a slight eye irritant; therefore, ocular exposure should be avoided when handling the pigment products.

Overall, given the engineering controls available to these workers, the low probability of exposure, the low concentration of the notified chemical present in imported pigment products (<5%), paint tinter (<0.5%) and final paints (<0.05%), and likely low systemic toxicity of the notified chemical, the health risk for workers involved in the tinter manufacture, paint formulation and paint application is assessed as low. Use of personal protective equipment will further reduce the risk.

Following drying of the paint, the chemical will be cross-linked with other paint components to form a stable film. In this form, the notified chemical is essentially unavailable for absorption and thus the health risk to workers from the notified chemical after paint application would be negligible.

The potential for exposure to the notified chemical during storage and transport would be considered low and would only be envisaged following accidental spillage or damage of the containers. Therefore, the health risk for transport workers would be assessed as low.

9.2.5. Public health – risk characterisation

Public exposure to the notified chemical will arise from DIY paint application and dermal contact from decorative surfaces coated with paint containing the notified chemical. However, given the intermittent exposure, i.e. limited to periods of home decorating and the low concentration of the notified chemical in final paints (<0.05%), the public health risk posed by the notified chemical is expected to be low. Once the paint has dried, the notified chemical is likely to be bound within a paint film and will not be available for separate exposure.

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 under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

10.2. Environmental risk assessment

A PEC/PNEC ratio cannot be determined. However, based on low environmental exposure resulting from its low import volume and widespread use, the likely risk to the aquatic environment is expected to be low.

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 No Significant Concern to public health when used as an ingredient in colourants for decorative paints.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the products containing 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 product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). 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 product:
 - Exhaust ventilation during tinter and paint manufacture.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical in the pigment product:
 - When manually weighing and charging the mixing vessel, avoid generating dust.
 - When filling containers and cleaning mixing equipment, prevent splashes and spills.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in the pigment product:
 - Protective clothing covering arms and legs or equivalent
 - Safety glasses
 - Protective gloves
 - Safety boots
 - Respiratory protection when manually weighing and charging the mixing vessel.

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 the paint tinter manufacturer to minimise environmental exposure during paint tinter manufacture:
 - Ensure bunding is in-place.
 - Do not use paint near drains or waterways.

Disposal

For Water based paints

- 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.”

For Solvent based paints

- 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 unwanted paint down the drain. Keep unwanted paint in sealed containers for disposal via special chemical 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 handled by containment and either swept up or an absorbent used if liquid, then placed in a sealable container ready for disposal.

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
 - the importation volume exceeds one tonne per annum notified chemical;
 - the notified chemical is introduced as an isolated chemical;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.

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