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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

IRGAZIN DPP RED 4013A

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

IRGAZIN DPP RED 4013A

1. APPLICANT

Ciba-Geigy Australia Ltd, 140 Bungaree Road, Pendle Hill, NSW 2145, have submitted a standard notification for assessment of IRGAZIN DPP RED 4013A.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, IRGAZIN DPP RED 4013A is not considered to be hazardous. Therefore, the details of chemical name, CAS number, molecular formula, structural formula, spectral data, purity, impurities and import volume have been exempted from publication in the Full Public Report and Summary Report.

Trade name: IRGAZIN DPP Red Rubine TR

Other name(s): IRGAZIN DPP Red 4013A
TKP 5005

Method of detection and determination:

Structure elucidation was carried out by Ultra-violet (UV), Infra-red (IR)and Nuclear Magnetic Resonance (NMR) spectroscopy.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Red powder
Odour:	No appreciable odour
Melting Point:	> 300°C
Relative Density:	1410 kg/m^3
Vapour Pressure:	Not determined (The notified substance is a solid substance with high melting point and high molecular weight)
Water Solubility:	< 0.1 mg/L at room temperature (determined by visual inspection after 6 days stirring, below detection limit, flask method
Fat Solubility:	< 1 mg/kg fat at 37°C

Partition Co-efficient (n-octanol/water) log $P_{o/w}$:	5.3 (estimated) 4.6 (measured) at 20.0-20.6°C
Hydrolysis as a function of pH:	Not determined (due to the low solubility of the test substance)
Adsorption/Desorption:	Not determined (The notifier argues that the method of use will not present any opportunities for release of any significant quantity of the substance into the environment which could result in contamination of soil. The EPA suggest that if release occurs, strong adsorption is expected.
Surface tension:	72.7 mN/m at 20°C (for the saturated solution)
Dissociation Constant:	Not determined
Flash Point:	Could not be ignited
Flammability Limits:	Not flammable
Decomposition Temperature:	> 180°C
Autoignition Temperature:	Not auto-flammable
Explosive Properties:	Not explosive
Reactivity/Stability:	Not reactive
Particle size:	100% v/v < 2μm

Comments on physico-chemical properties
The structure of the notified chemical does not contain functionalities likely to hydrolyse or dissociate. Test were performed according to OECD test guidelines and/or in conformity with EEC Directive 84/449 at facilities complying with OECD principles of good laboratory Practice.

4. PURITY OF THE CHEMICAL

Degree of purity : >60%

5. INDUSTRIAL USE

80-90% of IRGAZIN DPP Red 4013A will be used as a red pigment for the colouration of high performance industrial paints. 5-10% will be used in speciality printing inks and colouration of plastics.

The estimated estimated quantity of IRGAZIN DPP Red 4013A to be imported into Australia is 1-10 tonnes per year for the first five years.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported as an ingredient of a formulated product in sealed cardboard cartons (20 kg nett) with antistatic polythene liners.

Typically, manufacture of paints or printing inks involves a batch size of less than 100 kg every 2 - 4 months. Weighing of the pigment powder is normally conducted under local exhaust ventilation. Following weighing, the pigment is carefully added to a pre-mix vessel containing medium for complete `wetting out' of the particles. This is normally conducted under local exhaust ventilation and takes 30 minutes after which stirring is continued for 15 minutes. Dispersion of particles is then accomplished using a mill or attritor following which the dispersion is pumped to mixing tanks for blending with additives, solvent and resin. The final concentration of pigment in the inks is up to 20% and in the paints up to 10%.

Formulations are first established on a laboratory scale using less than 1 kg of pigment about once per year. The laboratory staff will also be involved in testing the incoming pigment powder every 2 - 4 months for about 1 hour. The laboratory staff also perform quality control checks on inks and paints during manufacture. It is estimated that less than 100 g of pigment is involved in these checks and exposure would occur every 2 - 4 months for periods of 1 - 2 hours.

Exposure to the pigment may occur during use of the formulated inks by printers or during use of the formulated paints by spray painters.

Plastics processors use ' masterbatches' or solid dispersions of pigments in a suitable carrier resin in the form of granules or pellets. To manufacture masterbatches, polymer, pigment powders, fillers and additives are weighed out and blended in sealed mixers. The blend, in the form of large resin particles to which the pigment particles are attached is discharged from the mixer into the hopper of an extruder which disperses the pigments in the softened polymer. Hot extruded strands are water cooled, pelletised, dried and packed into bags. The final concentration of pigment in the masterbatch is up to 20%.

A maximum of 60 plant operators and 20 laboratory staff are expected to be involved in manufacture of paint. Whereas for manufacture of ink and plastic processing and spray painting the corresponding figures are 60 and 170.

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7. PUBLIC EXPOSURE

Public exposure to the notified chemical as a result of contact with end-use products is not expected to occur as it will be embedded in the resin/polymer of printed materials, paint films or plastic materials. The notified chemical is practically insoluble in water, fat and common solvents, and therefore has negligible potential for migration from finished products, or dermal absorption.

8. ENVIRONMENTAL EXPOSURE

. Release

It is estimated that 5-10 industrial sites will be involved in the formulation of products containing the pigment. A further 50-150 spray painting, 5-10 printing and 5-10 plastics processing plants may become users of formulated products containing the notified substance. For all identified applications, negligible (<1 kg per site) amounts of the notified chemical will be released to the environment during formulation.

The concentration of the pigment in automotive and industrial paints is generally less than 10%. The primary users of formulations containing the pigment will be car manufacturers (OEM). Application will occur using an electrostatic multiple-gun spray painting process with an estimated overspray of

15%. In the repair industry overspray may be as high as 50%. In either case wastes will ultimately be consigned to landfill.

Speciality printing ink applications include inks for outdoor signs, metal decoration (cans) and security printing (bank notes, stamps and cheques).

The notified chemical may be used for the colouration of speciality plastics at a typical concentration of 0.1 to 0.2%. The market will be limited due to the relatively high cost of this chemical compared to existing chemicals. One potential application in the plastics area, is to replace the use of cadmium containing colourants.

. Fate

A 28 day test for biodegradation was performed according to OECD test guideline TG 301 B, at nominal concentrations of 10 and 20 $mg.L^{-1}$. The results show limited degradation of IRGAZIN DPP Red 4013A (<10% at both concentration studied), indicating that biodegradation in landfill is unlikely, particularly as encapsulation within the paint resin is expected.

During formulation of the paint, negligible (<1 kg per site) amounts of the notified chemical will be released to the environment. After application, the pigment becomes encapsulated within the drying resin of the paint formulation, thereby limiting the availability of pigment for release to the environment. The major routes of exposure to the environment will be during application to new cars and when repairs are made to damaged vehicles.

Application of paint to new cars involves the use of electrostatic spray techniques which minimise wastage due to overspray (estimated at <15%). This overspray is treated before discharge to the sewers by passage through interceptor pits. The pigment should associate with other solid residues and ultimately be disposed of by landfill.

During vehicle repairs, only part of the vehicle is repainted. However, spray application efficiency is poor, with wastage due to overspray estimated to be as high as 50%. Waste paint from panel repair shops may or may not be treated before disposal. However, quantities are small, and the properties of the pigment are such that it would become associated with sludge during sewage treatment or with soil at the site that receives overspray.

As automotive/industrial paints are formulated to be resistant to environmental exposure, erosion of the paint should be minimal. The notifier estimates that the top coat of a treated vehicle will contain < 200 g of the pigment. Therefore the amount released to the environment is likely to be insignificant and diffused over a wide area. Similar comments apply to polishing and cutting of cars surfaces by the public.

On disposal of the vehicle by recycling or landfill there should not be significant environmental releases of the new chemical. During recycling operations the surface coatings will be incinerated and at landfill the new chemical should not leach due to its low water solubility and moderately high K_{OW}. Additionally, the compound will be encapsulated in the paint resin which will reduce the leachability even further. In the event of incineration during recycling the release of water vapour and oxides of carbon and nitrogen is expected.

The environmental fate of the notified chemical, resulting from the identified minor use applications (speciality printing inks and as a pigment in plastics) will be similar to that identified for paints. The potential for environmental release is very limited, estimated at < 1 kg per annum at each formulation site. When used in speciality printing inks the pigment will become bound to the treated substrate, which will ultimately be recycled or consigned to landfill. During recycling, the ink and associated pigment released during processing is expected to be confined to the solid residues and sent to landfill. Leaching of the notified chemical in landfill is not expected from either the printed substrate or solids collected during recycling.

Pigmented plastics will ultimately be consigned to landfill. Leaching is unlikely due to the physico-chemical properties of the notified chemical identified above, and the immobilisation resulting from the encapsulation of the pigment within the cured polymer matrix (plastic).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of IRGAZIN DPP Red 4013A (containing approximately 97.5% notified chemical)

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD_{50} > 2000 mg/kg	(1)
Acute dermal toxicity	Rat	LD_{50} > 2000g/kg	(2)
Skin Irritation	Rabbit	Non-irritant	(3)
Eye irritation	Rabbit	Slight irritant	(4)
Skin sensitisation	Guinea pig	Non-sensitiser	(5)

9.1.1 Oral Toxicity (1)

This study was carried out inaccordance with EEC Directive 84/449/EEC (9).

A single dose of 2000 mg/kg of IRGAZIN DPP Red 4013A was administered by gavage to Albino Wistar rats (5/sex). The animals were observed at 1, 4 and 24 hours after dosing and subsequently once daily for 7 days. No deaths were noted during the study. All animals showed the expected gain in body weight and red discolouration of the skin, tail and faeces from day 3 onwards. Necropsy findings did not reveal any abnormalities.

It can be concluded that the acute LD_{50} for the notified chemical in rats is > 2000 mg/kg.

9.1.2 Dermal Toxicity (2)

This study was carried out in accordance with EEC Directive 84/449/EEC (9).

A single dose of 2000 mg/kg of IRGAZIN DPP Red 4013A was administered by semi-occlusive application to the shaved skin of Albino Wistar (5/sex) for 24 hours. The animals were observed at 1, 4 and 24 hours after dosing and subsequently once daily for 7 days after removal of the bandage. No deaths were noted during the study. Loss of body weight was noted in seven animals over the first week and in one animal over the second week. One animal exhibited yellow nasal discharge up to day one. All animals showed red discolouration of the skin which could be attributed to the red colour of the test substance. Necropsy findings .did not reveal any abnormalities.

It can be concluded that the acute dermal LD_{50} for the notified chemical in rats is > 2000 mg/kg.

9.1.3 Skin Irritation (3)

This study was conducted in accordance with EEC Directive 84/449/EEC (9).

Three New Zealand White male rabbits received a dose of 0.5 g of the notified chemical under a semi-occlusive gauze pad applied for 4 hours to shaved skin moistened with 0.5 ml of distilled water.

There were no clinical signs of ill health or toxicity in any rabbit up to 3 days post-treatment.

No erythema or oedema was observed in any animal up to 72 hours post-treatment.

It can be concluded that the notified chemical is not a skin irritant in rabbits.

9.1.4 Eye Irritation (4)

This study was conducted in accordance with EEC Directive 84/449/EEC (9).

Three New Zealand White rabbits received a dose of 21 mg of the notified chemical instilled into the lower everted lid of one eye of each animal.

There were no clinical signs of ill health or toxicity in any rabbit up to 3 days post-treatment.

No effects on the iris and cornea were seen in any animal.

Slight conjunctival redness was observed in one eye which disappeared on day 2. and chemosis were observed in one animal at 1 hour post-treatment. Well-defined redness and slight chemosis were observed in another animal up to 3 days post-treatment. In this animal redness was slight on day 4.

It can be concluded that the notified chemical is a slight eye irritant in rabbits.

9.1.5 Skin Sensitisation (5)

This study was conducted in accordance with EEC Directive 84/449/EEC (9) following the adjuvant method of Magnusson and Kligman (10) using female albino guinea pigs of the Dunkin/Hartley strain (10 control, 20 experimental). The strain is periodically tested for response to the known skin sensitiser formalin.

Induction was achieved with injection of a 5% w/w propylene glycol and topical exposure to a 50% w/w in vaseline of the notified chemical 7 days later. For topical challenge, concentrations of 50, 25 and 10% w/w in vaseline were employed.

Assessment of dermal irritation was not possible following topical induction with the 50% w/w concentration of the notified chemical.

Following challenge no oedema was observed in any test animal. Hoeever, erythema was difficult to score due to staining of the skin by the test substance.

It can be concluded that the notified chemical is not a skin sensitiser in guinea pigs.

9.2 Repeated Dose Toxicity (6)

This study was conducted in accordance with EEC Directive 84/449/EEC (9).

SPF-Wistar rats (5/sex/dose with an extra 5/sex given a 14 day recovery period at doses of 0 and 1000 mg/kg/day) received doses of 0, 50, 200 and 1000 mg/kg/day of the notified chemical in 1% polyethylene glycol by gavage.

No treatment-related clinical signs were noted.

Red coloured faeces were noted at all doses due to the fact that the test material is a pigment.

No mortality occurred during the study and no effects were observed on body weight, body weight gain and food consumption.

Some small statistically significant differences in haemotology, urinalysis and biochemistry parameters were noted but were not considered to be toxicologically significant.

No treatment-related differences in organ weights were observed. No treatment-related changes in macroscopic or microscopic pathology were observed.

It can be concluded that no target organ toxicity occurs in rats dosed repeatedly with the notified chemical for 28 days at doses up to 1000 mg/kg/day.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (7)

This study was conducted in accordance with guideline No. 471 (11). *Salmonella typhimurium* strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100 and *Escherichia coli* strain WP2 and WP2 *uvrA* were treated with doses up to 5000 μg/plate in the presence or absence of metabolic activation provided by rat liver S9.

No treatment-related increases in the number of protrophic back mutants were observed in any strain. Responses to the positive control mutagens Sodium azide, 4-Nitro-0-phenyl-diamine, Methyl methane sulfonate and 2-Aminoanthracene were as expected.

It can be concluded that the notified chemical is unlikely to be mutagenic in *Salmonella typhimurium* and *Escherichia coli*.

9.3.5 Chromosomal Aberrations in Chinese Hamster Ovary Cells In Vitro (8)

This study was performed in accordance with OECD guideline No. 473 (12).

Four sets of treatments were used and are summarised as follows:

Set 1: 4 hours treatment, +S9, harvest at 18 hours.
Set 2: 4 hours treatment, +S9, harvest at 18 hours.
Set 3: 4 hours treatment,+S9, harvest at 18 hours.
Set 4: 4 hours treatment, +S9, harvest at 28 hours.

All four experiments were repeated without S9 mix.

Doses were 0.6 and 3.0 μg/ml for sets 1 and 2 and 6.0 μg/ml for sets 3 and 4.

No statistically significant increases in chromosomal aberrations were observed with or without metabolic activation provided by rat liver S9.

It can be concluded that the notified chemical is not clastogenic in CHO cells *in vitro*.

9.4 Overall Assessment of Toxicological Data

The notified chemical exhibited low oral and dermal toxicity in rats, did not exhibit toxic effects when administered orally to rats for 28 days, was not a skin irritant in rabbits, was not a skin sensitiser in guinea pigs, was not mutagenic in bacteria and was not clastogenic in CHO cells in culture. However, the notified chemical was a slight eye irritant in rabbits.

On the basis of submitted data, the notified chemical would not be classsified as hazardous in accordance with *Approved Criteria for Classifying Hazardous Substances* (13).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following tests to assess the environmental effects of IRGAZIN DPP Red 4013A were performed according to OECD and EEC test guidelines, results are summarised in Table 1.

Table 1. Concentrations are actual, unless otherwise stated.

Species	Test	Result
Carp *Cyprinus carpio*	96 hour acute OECD TG 203	NOEC > 7.3 $mg.L^{-1}$ the max. concentration at the end of the test. LC_{50} > max. solubility of the pigment in water
Water flea *Daphnia magna*	48 hour acute OECD TG 202	EC_{50} > max. solubility of the pigment in water
Algae *Scenedesmus subspicatus*	Algal growth inhibition OECD TG 201	NOEC & EC_{50} > max. solubility of the pigment in water
Activated sludge	30 minute respiration inhibitory test OECD TG 209	no significant (<10%) inhibition was recorded max. test concentration 100 $mg.L^{-1}$

In the fish study, Cremophor RH40 (100 $mg.L^{-1}$) was used as a dispersing agent. Two test solutions were trialled (i) a supersaturated solution (100 $mg.L^{-1}$, nominal); and (ii) its filtrate (filtered through a filter paper). Both trial solutions were observed to have an opaque dark red to red appearance. For the supersaturated solution the concentration of the pigment in solution was rapidly depleted from an initial (measured) value of 62 $mg.L^{-1}$ to 7.3 $mg.L^{-1}$ after 96 hours. During the same period the filtrate concentration decreased from 8.5 $mg.L^{-1}$ to 5.9 $mg.L^{-1}$. The Daphnia tests were performed using the same vehicle and nominal concentrations as for the fish studies but the actual concentrations at the completion of the 48 hour study were 45 $mg.L^{-1}$ and 4.8 $mg.L^{-1}$ for the supersaturated and filtrate test solutions respectively.

The results reported above indicate that at the maximum water concentration, the notified chemical should have no adverse effects on aquatic organisms. Both the fish and daphnia studies reported made no direct reference to the presence of solids or the occurrence of precipitation during testing. However, the algal study noted that test substance particles were found floating at the surface of all test solutions. The rapid reduction in concentration of the test solutions (measured), probably through adsorption to the vessel walls, and the observation of floating particulates, suggest that partitioning of the notified chemical to the sediment is likely, thereby limiting its potential for exposure.

The 30 minute respiration inhibition test for activated sludge showed no significant inhibition (< 10%), indicating microbial populations in sewage treatment works are unlikely to be adversely effected by the pigment.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard of IRGAZIN DPP Red 4013A can be rated as negligible. The proposed application and associated usage patterns will limit the environmental exposure to negligible levels. Release of unbound pigment is expected to be < 1 kg at each formulation site (maximum of 10).

The greatest exposure will occur from residues from spray paint applications which will ultimately be consigned to landfill. Similarly, the painted articles will be disposed of by landfill or recycled at the

end of their useful lives. In landfill the pigment will not leach due to its insolubility. Furthermore, the encapsulation of the pigment within the paint resin further reduces its leachability.

The low level environmental exposure of the pigment as a result of normal use, together with its lack of significant biological activity, indicate the environmental hazard should be negligible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical has the potential to cause slight eye irritation possibly as a result of mechanical damage. As there is a sizable respirable fraction there is potential for the notified chemical to enter the lungs if a dust cloud is formed during its use or as a result of accidental damage to the cardboard containers in which the pigment is imported.

The notified chemical appears likely to be used infrequently in low amounts in the manufacture of inks, paints and plastics. There is potential to generate dust clouds during weighing and during addition to the medium in which the pigment is dispersed for the manufacture of inks and paints. As local exhaust ventilation is commonly used during these operations which are performed only at 2 - 4 month intervals exposure is expected to be low. In the manufacture of plastics there would appear to be a possibility of exposure on transfer of the blended pigment/polymer mix to the hopper of an extruder. However, as the pigment particles are firmly attached to polymer granules by electrostatic attraction, respiratory exposure is unlikely.

The risk of adverse occupational health effects associated with use of the notified chemical is expected to be low. However, the fact that the notified chemical of respirable size suggests that a respirator should always be used if there is any potential for the formation of dust clouds such as during weighing and mixing operations.

Public exposure to the notified chemical as a result of contact with end-use products is not expected to occur as it will be embedded in the resin/polymer of printed materials, paint films or plastic materials. If public exposure were to occur exposure levels would be low, and the low fat solubility of the notified chemical suggests the dermal absorption is unlikely. There is negligible risk to public safety resulting from use of the notified chemical.

13. RECOMMENDATIONS

To minimise occupational exposureto IRGAZIN DPP Red 4013A the following guidelines and precautions should be observed:

during weighing and mixing operations and cleaning up of spills a particulate filter respirator which conforms to and is used in accordance with Australian Standards (AS) for respiratory protection (AS1715, AS 1716) (14,15) should be worn;

. if engineering controls and work practices are insufficient to reduce exposure to a safe level, then personal protective devices which conform to and are used in accordance with Australian Standards for eye protection (AS 1336, AS 1337) (16,17), impermeable gloves (AS 2161) (18) and overalls should be worn;

. good work practices should be employed to avoid dust generation and to minimise spills;

. good personal hygeine should be practised;

. a copy of the Material Safety Data Sheet should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The attached Material Safety Data Sheet (MSDS) for IRGAZIN DPP Red 4013A was provided in Worksafe Australia format (19).

This MSDS was provided by Ciba-Geigy Australia Ltd as part of their notification statement.. It is reproduced here as a matter of public record. IRGAZIN DPP Red 4013A The accuracy of this information remains the responsibility of Ciba-Geigy Australia Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of IRGAZIN DPP Red 4013A shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. Should the use pattern change such that exposure to dust increases significantly, a secondary notification will be required. No other specific conditions are prescribed.

16. REFERENCES

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3. *Irgazin DPP Red 4013A, Skin Irritation to the Rabbit*, Project No. 327216, data on file, RCC NOTOX B.V., Netherlands, 1992.

4. *Irgazin DPP Red 4013A, Eye Irritation to the Rabbit*, Project No. 327227, data on file, RCC NOTOX B.V., Netherlands, 1992.

5. *Irgazin DPP Red 4013A, Skin Sensitisation in the Guinea-Pig*, Project No. 327328, data on file, RCC NOTOX B.V., Netherlands, 1992,.

6. *Irgazin DPP Red 4013A, Four-Week Oral Toxicity Study in the Rat with Two-Week Recovery Period*, Project No. 325620, data on file, RCC NOTOX B.V., Netherlands, 1993.

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8. *Irgazin DPP Red 4013A, Analysis of Metaphase Chromosomes Obtained from CHO Cells Cultured In Vitro*, Project No. 302321, data on file, RCC NOTOX B.V., Netherlands, 1993.

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17. Australian Standard 1337-1984, Eye Protectors for Industrial Applications, Standards Association of Australia Publ., Sydney, 1984.

18. Australian Standard 2161-1978, "Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)", Standards Association of Australia Publ., Sydney 1978.

19. National Occupational Health and Safety Commission, National Code of Practice for the Preperation of Material Safety Data Sheets, [NOHSC:2011(1994)].