File No: NA/211

Date: 19 October 1994

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

IRGAZIN DPP ORANGE 398A

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989,* and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Human Services and Health.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

IRGAZIN DPP ORANGE 398A

1. APPLICANT

Ciba-Geigy Australia Ltd, 140 Bungaree Rd, Pendle Hill, NSW, 2145.

2. IDENTITY OF THE CHEMICAL

Irgazin DPP Orange 398A is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, exact molecular weight and import volume, chemical composition and spectral data have been exempted from publication in the Full Public Report and the Summary Report

Other name: TKP 50 006

Trade name: Irgazin DPP Orange 398A, CROMOPHTAL DPP Orange TR

Molecular weight: < 1000

Method of detection and determination:

UV/Vis and IR spectroscopy, Mass spectrometry, HPLC

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Orange powder
Melting Point:	> 360°C
Relative Density D_4^{20}:	1.377
Vapour Pressure:	2 X 10^{-10} Pa at 25°C
Water Solubility:	1.22 X 10^{-5} g/L at 20°C
Fat Solubility:	< 0.059 mg/100g fat at 37°C
Partition Co-efficient (n-octanol/water) log P_{OW}:	0.2 - 0.6 (calculated)
Surface Tension:	49.9 $mN.m^{-1}$
Flammability Limits:	Non-flammable
Autoignition Temperature:	> 410 °C
Explosive Properties:	Non-explosive

Reactivity/Stability: No oxidising properties. No incompatibility with other substances known.

Particle size distribution:

< 4 μm	23.6%
< 8 μm	40.6%
< 16 μm	67.8%
< 32 μm	95.1%
< 48 μm	100.0%

Comments on physico-chemical properties

The tests for hydrolytic stability, soil adsorption/ desorption, and dissociation, were not performed. The partition coefficient is lower than would be expected for a chemical of low water solubility. It is argued that the water solubility of the pigment is extremely low and the entry of the pigment into the soil is expected to be at very low levels. Also, it is argued that the test for hydrolytic stability is not applicable because of its very low water solubility, and the pigment structure does not contain functionalities likely to hydrolyse or dissociate in water. The surface tension is considered low for a compound that is sparingly soluble in water and the notifier considers that it is likely to be due to the effect of water soluble impurities or the presence of suspended particulate matter. These arguments are considered acceptable.

4. PURITY OF THE CHEMICAL

Degree of purity: 97%

Impurities: Two major impurities were identified (0.53% and 2.01%) and a number of minor impurities (0.29% in total

Additives/Adjuvants: None

5. INDUSTRIAL USE

The notified chemical is to be used as a colouring agent (pigment) for printing inks, mass colouration of plastics and industrial paints. The major use of the notified chemical (about 80 - 90%) is in the manufacture of specialty printing inks with minor uses in the manufacture of paints (about 5 -15%) and plastics (< 5%).

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported in sealed cardboard boxes (20 kg nett) with antistatic polythene liners at a rate of 1 - 10 tonnes per year for the first 5 years.

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 to10%.

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 36 plant operators and 12 laboratory staff are expected to be involved in ink manufacture whereas for manufacture of paint and plastic the corresponding figures are 30 and 10.

7. PUBLIC EXPOSURE

Public exposure resulting from storage and distribution of the notified chemical is not expected to occur. Significant public exposure to the notified chemical resulting from its industrial usage or from its disposal by incineration or landfill is not expected to occur.

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, lacquer/paint film or plastic materials.

8. ENVIRONMENTAL EXPOSURE

. Release

Common to all industry applications, losses of the dry pigment could occur on addition of the pigment in the pre-mix stage due to dust suspension, or in storage from accidental spills.

Based on 1000 kg of imported pigment, it is estimated that less than 10 kg of the pigment might be lost as waste in reformulation into speciality printing inks. Such losses in reformulation into paints and plastic masterbatches are expected to be less than 1 kg per year for each of those industries.

When considering all possible applications and the worse case scenario, the loss of pigment might reach about 3% of total imported product. Most of this loss would be due to the cleaning of printing presses and other equipment used in the printing industry, with the solvents used to clean the equipment being recycled and the residue (pigment and resin) trapped and disposed of through landfill. Any residue would readily adhere to substrates because of the resin. Less than 1 kg of pigment would be expected to be lost per run. The application of industrial paints would be by spraying. The loss through over-spraying is estimated to be less than 10 kg per annum for all paint applications. The use and application of coloured masterbatch containing the pigment is expected to be less than 1 kg per annum. The losses would be at a number of different locations.

The ability of the pigment to be biodegraded was tested using OECD Test Method 301B. The test result (-5% and 0% biodegradation at nominal concentrations of 10 mg/L and 20 mg/L, respectively) indicated the pigment was *not readily biodegradable*. Inherent biodegradability is uncertain.

The pigment is likely to have a high affinity for soil and sediment. Also, no bioaccumulation of the pigment is expected since its large molecular size is likely to inhibit membrane permeability and

prevent uptake during exposure (1,2). This, together with the low probability of its entry into surface and ground waters because of its very low water solubility, and its designated end use by specialist workers, suggests that the loss of the pigment to the environment will be very limited.

. Fate

The pigment will be transported in sealed cardboard boxes with antistatic liner. Risks from accidental spillage appear small as the pigment will be freighted by air direct to major printing ink producers.

The Material Safety Data Sheet (MSDS) gives directions for clean-up of minor spills, but refers the reader to a "competent authority" in the event of a major spill. In the event of a minor spill, the MSDS states that the material should be cleaned up mechanically and deposited in a suitable container for disposal by landfill or incineration, and disposed in accordance with State Regulations. Importantly, the MSDS cautions the reader that the material should not contaminate soils, drains or waterways. Also, the MSDS highlights that disposal by incineration should be performed in modern equipment capable of attaining a temperature of 800°C and equipped with suitable state-of-the-art gas purification devices to deal with possible toxic emissions (e.g. hydrogen cyanide).

It is stated that any waste generated in the reformulation of the pigment will be disposed of in landfill. Further, in the application of the pigment in its end-use, the chemical will be completely encapsulated by a polymer matrix.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Irgazin DPP Orange 398A

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD50 > 5000 mg/kg	(3)
Acute dermal toxicity	Rat	LD50 > 2000 mg/kg	(4)
Skin Irritation	Rabbit	Non-irritant	(5)
Eye irritation	Rabbit	Slight irritant	(6)
Skin sensitisation	Guinea pig	Non-sensitiser	(7)

9.1.1 Oral Toxicity (3)

This study was conducted in accordance with EEC Directive 84/449/EEC (OJ No. L251, 19.09.84) (8).

Sprague-Dawley rats (5/sex) received a single oral dose of Irgazin DPP Orange 398A at 5000 mg/kg in 1% w/v aqueous methylcellulose by gavage.

Pilo-erection was observed in all rats. Recovery was complete by day 2. Orange/brown faeces were observed on day 2 only. There were no deaths up to day 15 and no macroscopic abnormalities were observed for animals killed at the conclusion of the study on day 15.

It can be concluded that the acute oral LD_{50} for the notified chemical in rats is > 5000 mg/kg.

9.1.2 Dermal Toxicity (4)

This study was conducted in accordance with EEC Directive 84/449/EEC (OJ No. L251, 19.09.84) (8).

Sprague-Dawley rats (5/sex) received a dose of Irgazin Orange DPP at 2000 mg/kg applied under a gauze patch.

No clinical signs of toxicity were noted, no deaths occurred and no macroscopic abnormalities were observed at the termination of the study on day 15. Orange colouration of the skin by the notified chemical prevented an adequate estimation of erythema or oedema.

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 (5)

This study was conducted in accordance with EEC Directive 84/449/EEC (OJ No. L251, 19.09.84) (8).

Three New Zealand White 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 (6)

This study was conducted in accordance with EEC Directive 84/449/EEC (OJ No. L251, 19.09.84) (8).

Three New Zealand White rabbits received a dose of 50 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 7 days post-treatment.

No effects on the iris were seen in any animal.

Slight corneal opacity was observed in one animal at 24 and 48 hours post-treatment.

Slight conjunctival redness 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 (7)

This study was conducted in accordance with EEC Directive 84/449/EEC (OJ No. L251, 19.09.84) (8) following the adjuvant method of Magnusson and Kligman (9) using female albino guinea pigs of the Dunkin/Hartley strain (20 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 solution and topical exposure to a 50% w/w aqueous solution of the notified chemical 7 days later. For topical challenge, concentrations of 50 and 25% w/w 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 erythema or oedema was observed in any test animal.

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

9.2 Repeated Dose Toxicity (10)

This study was conducted in accordance with EEC Directive 84/449/EEC (OJ No. L251, 19.09.84) (8).

Sprague-Dawley 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, 15, 150 and 1000 mg/kg/day of the notified chemical in 1% aqueous methylcellulose 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 (11)

This study was conducted in accordance with guideline No. 471 (12). *Salmonella typhimurium* strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100 and *Escherichia coli* strain 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 N-ethyl-N'-nitro-N-nitrosoguanidine, 9-aminoacridine, 2-nitrofluorene 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*.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (13)

This study was conducted in accordance with OECD guideline No. 474 (14) using Charles River CD-1 mice (15/sex/dose group, 1000 PCE scored per animal).

No treatment-related increases in the frequency of micronuclei were observed at a dose of 5000 mg/kg with sampling times of 24, 48 and 72 hours post-treatment. The positive control substance mitomycin C induced micronuclei as expected.

It can be concluded that the notified chemical is unlikely to be clastogenic in mice.

9.3.3 In Vivo Rat Liver DNA Repair Test (15)

This study was conducted using procedures from OECD guideline No. 482 (16) and techniques recommended by the American Society for Testing and Materials (17).

Sprague-Dawley rats (4/dose group) received doses of 0, 600 or 2000 mg/kg by gavage and expression times of 2 and 14 hours were used. No treatment-related increases nuclear grain count were observed. Highly significant increases in the nuclear grain count were observed with the positive control substances dimethylnitrosamine (2 hour expression time) and 2-acetylaminofluorene (14 hour expression time).

It can be concluded that the notified chemical is unlikely to induce DNA damage in the rat liver following oral administration.

9.3.4 Chromosomal Aberrations in Human Lymphocytes Cultured In Vitro (18)

This study was performed in accordance with OECD guideline No. 473 (19).

Following phytohaemagglutinin stimulation of freshly isolated human lymphocytes for 48 hours, cells were incubated with up to 5000 μg/ml of the notified chemical in the presence or absence of rat liver S9 for 18 or 32 hours. Following incubation in fresh medium for 15 or 29 hours, mitotic activity was arrested prior to cell fixation.

A statistically significant increase in the proportion of cells with chromosomal aberrations was observed at the 18 hour harvest time in the absence of rat liver S9. No increase was observed in the presence of rat liver S9 or at the 32 hour time point. Both positive control compounds, ethyl methane sulphonate and cyclophosphamide caused large statistically significant increases in the proportion of aberrant cells.

It can be concluded that the notified chemical is clastogenic in cultured human lymphocytes.

9.3.5 Chromosomal Aberrations in Chinese Hamster Ovary Cells In Vitro (20)

This study was performed in accordance with OECD guideline No. 473 (19).

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

Set 1: 6 hours treatment, +S9, harvest at 24 hours.
Set 2: 6 hours treatment, -S9, harvest at 24 hours.
Set 3: 24 hours treatment, -S9, harvest at 24 hours.
Set 4: 48 hours treatment, -S9, harvest at 48 hours.

Doses were 39.1, 78.1 or 156.3 μg/ml for sets 1 and 2 and 19.5, 39.1 and 78.1 μg/ml for sets 3 and 4.

No statistically significant increases in chromosomal aberrations were observed in the presence of metabolic activation provided by rat liver S9. However, statistically significant increases in chromosomal aberrations were observed in set 2 at 39.1 and 156.3 μg/ml and in set 4 at 19.5 μg/ml.

As the increases in the frequency of chromosomal aberrations induced by the notified chemical do not appear to be dose-related it is not possible to conclude unequivocally that it is 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 mice. However, the notified chemical was a slight eye irritant in rabbits and was clastogenic in human lymphocytes in culture. No conclusions could be drawn from the experiments on induction of chromosomal aberrations in CHO cells in culture. In the absence of positive results in an *in vivo* test for genotoxicity, the notified chemical cannot be classified as a mutagen (21).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The ecotoxicity studies were conducted using Irgazin DPP Orange 398A (97% purity) dissolved in 10% Tween 80- tetrahydrofuran. Some loss of the pigment was noted in the fish and water flea tests. The results in table 2 were provided by the notifier. The results show the pigment to be nontoxic to fish and daphnids at the upper limits of the dye's solubility when using a dispersing agent.

An algae growth inhibition test was not performed. It is stated that "such a test appears to be inappropriate in the case of strongly coloured substances (like this pigment) which are practically insoluble in water (12.2 µg/L). Any change in growth may be due to a reduction in light intensity and not necessarily due to any algae toxicity of the substance". While any effect on algae growth due to colouration of the water might lead to an undesirable environmental impact, such an event is considered unlikely due to the pigment's low water solubility and low estimate of loss to the environment.

The influence of the pigment on respiration of activated sludge was tested under aerobic conditions according to OECD Test Method 209. A concentration of > 1 mg/L caused no inhibition of bacterial respiration processes.

Table 2 Ecotoxicity test results

Species	Test	Result
Rainbow Trout (Oncorynchus mykiss)	96 h acute	LC50 > 0.73 mg/L (mean of measured concentration of pigment in fresh and expired media)
Water Flea (Daphnia magna)	48 h acute	EC50 > 0.25 mg/L (mean of measured concentration of pigment in expired media only due to substantial loss of pigment through test)
Activated Sludge	Respiration Inhibition Test	EC50 > 1.0 mg/L (30 min) and > 1.0 mg/L (3h) (nominal concentrations)

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

It is stated that "the possibility of release to the environment of Irgazin DPP Orange 398A is likely to occur only from spills during transport of formulated products containing the notified substance, or in the disposal of material spilt in the workplace". Further, these events "are not considered significant events, as the concentration of Irgazin DPP Orange 398A in such products is so small." It is further

stated that in considering the worse case scenario, there is likely to be a loss per annum of 50 kg of the pigment, with disposal likely to be through landfill.

Given 1) the small quantity of pigment estimated to be disposed of to landfill, 2) the lack of any marked effect of the pigment on aquatic life, 3) the likely low level of exposure of aquatic life to the pigment, 4) the likely high affinity of the pigment with soils and sediment, and 5) the unlikely possibility that the pigment will bioaccumulate, the substance appears to pose little environmental hazard.

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. It also appears to be weakly genotoxic *in vitro*. However, as there were no positive *in* vivo tests the notified chemical cannot be classified as a mutagen under the National Occupational Health and Safety Commission' s National Model Regulations for Control of Workplace Hazardous Substances (21). 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 is 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, lacquer/paint film or in plastic materials. If public exposure were to occur exposure levels would be low, and the low fat solubility of the notified chemical suggests that dermal absorption is unlikely. There is negligible risk to public safety resulting from use of the notified chemical.

13. RECOMMENDATIONS

To minimise occupational exposure to Irgazin DPP Orange 398A 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) (22,23) 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) (24,25), impermeable gloves (AS 2161) (26) and protective clothing 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 Material Safety Data Sheet (MSDS) for Irgazin DPP Orange 398A was provided in Worksafe Australia format (27).

This MSDS was provided by Ciba-Geigy Australia Ltd as part of their notification statement. 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 Orange 398A 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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