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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

IRGAZIN DPP ORANGE 16AOA

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

IRGAZIN DPP ORANGE 16AOA

1. APPLICANT

Ciba-Geigy Australia Ltd of 140 Bungaree Road, Pendle Hill, NSW 2145 has submitted a standard notification for the assessment of IRGAZIN DPP Orange 16AOA.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, IRGAZIN DPP Orange 16AOA is considered to be non-hazardous. Therefore, the chemical identity, composition and manufacturing volume have been exempted from publication in the Full Public Report and the Summary Report.

Trade names: IRGAZIN DPP Orange 16AOA
TKP 50007

Method of detection and determination:

Techniques used are Infrared, UV-VIS and mass spectoscopy. No suitable technique was found that could determine the main component of IRGAZIN DPP Orange 16AOA. This was determined indirectly by subtracting the water content and extractable matter from 100%.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Orange powder
Odour:	None
Melting Point:	> 400°C. The melting point was determined using a Differential Scanning Calorimeter. The sample did not melt, and displayed no signs of decomposition up to 400°C.
Boiling Point:	509°C (calculated)
Specific Gravity:	1.14×10^3 kg/m^3 at 21°C
Vapour Pressure:	2.5×10^{-9} Pa at 25°C. The vapour pressure figure was calculated using the modified Watson correlation, and was based on the calculated boiling point (see above).
Water Solubility:	< 0.0001 g/L at 20°C
Fat Solubility:	< 0.0002 g/100 g fat at 37°C
Partition Co-efficient (n-octanol/water) log P_{ow}:	5
Hydrolysis as a function of pH:	Not performed due to low water solubility. Functionalities unlikely to hydrolyse.

Adsorption/Desorption:	Not performed due to low water solubility. Method of use will restrict entry of the notified substance into the soil.
Dissociation Constant:	Not performed due to low water solubility. Functionalities unlikely to dissociate.
Flash Point:	Not determined
Flammability Limits:	Not highly flammable
Combustion Products:	Not determined
Decomposition Temperature:	> 400°C
Decomposition Products:	Not determined
Autoignition Temperature:	377°C
Explosive Properties:	Non-explosive when exposed to flame, shock or friction.
Reactivity/Stability:	Not expected to react exothermically with flammable material due to absence of reactive groups which could support oxidation. Does not react with water or moist air.
Particle size distribution:	99.9% < 2 µm Median diameter = 0.326 µm No particles > 63 µm

Comments on physico-chemical data:

The boiling point was calculated using Meissner's method as part of the vapour pressure determination, and appears to be a considerable under-estimate based on the melting point.

4. PURITY OF THE CHEMICAL

Degree of purity: > 60%

5. INDUSTRIAL USE

IRGAZIN DPP Orange 16AOA will be used largely as a coloured pigment in the manufacture of industrial and decorative paints, including automotive paints applied at car manufacturers and repairers. Printing applications will use up to 5% of the notified chemical and will include outdoor advertising, metal decoration , vinyl film, speciality packaging and security printing. Small volumes (up to 5%) of IRGAZIN DPP Orange 16AOA also may be used for plastic colouration.

The pigment will only be used where a high degree of colour fastness is required. The majority of customers are in Melbourne, but there may be others throughout Australia.

No incidences of adverse health affects have been reported from other countries that manufacture or use IRGAZIN DPP Orange 16AOA.

6. OCCUPATIONAL EXPOSURE

The pigment will arrive by air freight in 20 kg cardboard boxes with antistatic polyethylene liners specifically suitable for discharge where solvent vapours are present.

Pigments are stored in dry areas on pallets and exposure to store workers is likely only in the event of bags being broken.

Typically, the sequence of events in production of paints, inks and plastics is as follows. Raw material is delivered to the stores and quality checked. Using multiples of whole bags of the pigment where possible (thus reducing exposure) quantities are weighed on mechanical scales or load cells. This is added to the pre-mix vessel containing other raw materials. Aerosol generation is possible at this stage, and is the major potential source of exposure to this chemical. Local exhaust ventilation will be used to keep dust levels within the Worksafe exposure standard (TWA = 10 mg/m^3 for respirable dusts) (1). Normally the pigment is added in stages over about 30 minutes and mixing performed each time to ensure thorough wetting of all of the particles. After the pigment is completely wet, mixing continues for a further 15 minutes prior to dispersion on bead mills, attritors, or ball mills. After dispersion, the mill is sampled and checked prior to being discharged and pumped to mixing tanks where further blending processes may occur. After further processing, the mixtures are checked and adjusted if necessary prior to packaging of the formulated product.

Manufacturing processes such as this would normally require less than 100 kg of pigment per batch and be performed every 2 - 4 months per establishment. The final formulations will normally contain only a few percent of the notified chemical.

During the initial stages of establishing new formulations, trials are performed in the laboratories using small amounts (<1 kg) of the notified chemical. Such testing is expected to take place once annually. Laboratory staff will also be involved in testing IRGAZIN DPP Orange 16AOA when it arrives at the stores and < 100 g is likely to be tested every 2 or 4 months.

Laboratory staff may experience exposure to the notified chemical via skin or eye contact or inhalation when performing quality checks before, during and after the reformulation processes.

The process of masterbatch (encapsulation) involves blending of the weighed polymer with pigments and other ingredients in sealed mixers. An extrusion process is then performed which completely encapsulates the pigment into the molten polymer. Extruded strands are then cooled, pelletised and packaged.

It is estimated that a maximum of 80 workers in up to 10 establishments may potentially be exposed to IRGAZIN DPP Orange 16AOA during development, testing and reformulation. An estimated 30 spray painters, numerous house painters and 20 printers may be exposed to the notified chemical during use of the formulated products. IRGAZIN DPP Orange 16AOA will at this stage be incorporated into a resin, varnish, solvent or oil mix. Plastic industry process workers will be handling the notified chemical only after it has been encapsulated within a polymer and are therefore not expected to experience exposure.

7. PUBLIC EXPOSURE

While public contact with materials coated with or containing the notified chemical is likely to be high, public exposure to the chemical is expected to be low. Once the pigment is incorporated into paint, printing ink or plastics, it will be encapsulated in the resin/polymer of paint films, printed materials or plastic materials. Migration of the paint from these articles is extremely unlikely.

While the public may come into contact with the pigment during the application of decorative paints, the low levels of pigment in such paints along with the low fat and water solubility, non volatility and low toxicity suggest that it is unlikely to pose a risk to public health.

In the case of accidental spillage during transport, the public may be exposed to the notified chemical. This is minimised by the recommended practices for storage and transportation. Emergency procedures or containment and clean-up of accidental spills are available and should be followed.

8. ENVIRONMENTAL EXPOSURE

. Release

It is anticipated that wastes produced as a result of formulation of the pigment will be minimal, with losses of less that 1 kg per year predicted. Such losses will be either trapped in air filters or in water filtration, and would be disposed of either by incineration or to landfill.

New automotive paints will be applied by spraying, with an estimated 15% of paint applied lost as overspray. As such oversprays will contain solvents, they will pass through extraction scrubbers. Trapped material, estimated at approximately 0.03 kg of pigment per vehicle will be collected and landfilled.

Wastes in the case of vehicle repairs are estimated to be much higher, with wastage of up to 50% anticipated. However, as generally only part of the car will be re-painted during repairs, amounts of pigment passing to landfill from this source are estimated to be approximately 0.05 kg per vehicle repaired.

When painted articles are disposed of, it is anticipated that very little of the pigment will be released to the environment. In addition, very little of the pigment is expected to be released as a result of photodegradation or normal breakdown during the life of the vehicles. These releases would be very diverse and are expected to be minor. Each typical motor vehicle top coat will contain about 2 kg of paint, or less than 0.2 kg of the pigment. Incineration or landfilling of painted items is not expected to release major amounts of the pigment to the environment.

The pigment will also be used as a tint (1-2%) in high quality decorative paints. Painted surfaces for this application are thought to contain < 1.5 g of pigment per square metre, at an estimated coverage of 14-16 square meters per litre of paint applied. Paints will be applied by brushes and rollers, with clean-up being either with water or solvents, depending on the type of paint. Washings as a result of cleanup will pass to sewers, at an estimated 1-2 g of pigment per painted item.

Disposal of painted items, empty cans and other solid wastes to landfill is again expected to yield minimal amounts of the pigment. Release as a result of weathering of the applied paint will also be minimal.

Printing inks will use a small proportion of the notified substance (< 5%). Such inks will be used for outdoor advertising signs and posters, metal decoration, vinyl film inks and security printing of bank notes, stamps and cheques. Each article is thought to contain 1-2 g of pigment per square metre. An estimated loss of less than 1 kg per year is anticipated from these uses.

Plastics colouration is also a small use for the notified substance. However, due to the relatively high cost of use of this pigment, only a small range of speciality products will utilise the colouring, in situations where high light fastness and processing stability are required. When used in polypropylene plastics, typical concentrations of the pigment will be about 0.1-0.2%. An estimated loss of less than 1 kg per year is anticipated from these uses.

Finally, losses expected from masterbatch use and application are also expected to be small, with less than 1 kg per year expected to be disposed of to either waterways or landfill.

. Fate

The low water solubility of the notified substance means that it should not easily move out of landfill areas after it has been deposited. Absence of adsorption/desorption makes analysis of the potential

behaviour of the substance in waterways difficult, but given the low solubility of the substance, it will most likely settle out onto sediments.

The notifier specifies that incineration of wastes should be conducted using modern incinerators 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.

Biodegradation

The substance was examined for biodegradation potential using EEC Directive 92/69, Part C.4-C (a modified Sturm test), (2) and OECD Test Guideline 301B. No biodegradation occurred over the 28 day study period. The reference substance, aniline, degraded by 72.6% over the same period. The test substance showed no inhibitory effect on the micro-organisms in the test vessels.

Bioaccumulation

No testing of the bioaccumulation potential was conducted. The partition coefficient lies in the area of concern (ie log P_{OW} = 5), but the low water and fat solubility should mean that the substance will not bioaccumulate.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of IRGAZIN DPP Orange 16AOA

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD_{50} > 2000 mg/kg	(3)
Acute dermal toxicity	Rat	LD_{50} > 2000 mg/kg	(4)
Skin Irritation	Rabbit	Non-irritant	(5)
Eye irritation	Rabbit	Mild irritant	(6)
Skin sensitisation	Guinea-pig	Non-sensitiser	(7)

9.1.1 Oral Toxicity (3)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 401*.

Albino Tif: RAI f rats (5 per sex) were administered (by gavage) a single dose of 2000 mg/kg IRGAZIN DPP Orange 16AOA in 0.5% w/v carboxymethylcellulose in 0.1% aqueous polysorbate 80. Animals were observed for a period of 14 days after which necropsy was performed.

All animals exhibited slight to moderate piloerection, hunched posture and dyspnea from 1 hour after treatment to up to 4 days later. One female had spotted lungs on necropsy. No other clinical signs, deaths, macroscopic changes or changes in body weight were observed in any animal.

It was concluded that the oral LD_{50} of IRGAZIN DPP Orange 16AOA was > 2000 mg/kg.

9.1.2 Dermal Toxicity (4)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 402*.

Wistar-derived rats (5 per sex) were administered a single dose of 2000 mg/kg IRGAZIN DPP Orange 16AOA by dermal application.

On day one of the procedure the test substance was applied evenly to a portion of a shaved skin area. This was covered by a semi-occlusive dressing. IRGAZIN DPP Orange 16AOA was diluted in corn oil and animals received 4 ml test substance per kg at a dose of 2000 mg/kg. Twenty four hours after application the skin was washed and dried. The animals were then observed for a period of 14 days after which necropsy was performed.

No mortality or macroscopic abnormalities were observed during the study. The skin of all animals was stained red at the application site and remained so until day 13 or 14.

It was concluded that the dermal LD_{50} of IRGAZIN DPP Orange 16AOA to rats was > 2000 mg/kg.

9.1.3 Skin Irritation (5)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 404.*

New Zealand White rabbits (three males) were administered a single dose of 0.5 g of IRGAZIN DPP Orange 16AOA moistened with 0.5% w/v carboxymethylcellulose in 0.1% w/v aqueous polysorbate 80.

On day one of the procedure the test substance was applied to a portion of the shaved area and covered with a semi-occlusive dressing. The test substance remained on the skin for four hours after which time it was removed with lukewarm tap water. Animals were then observed at 1, 24, 48 and 72 hours after removal of the dressing.

All three animals had orange skin discolouration which was present one hour after patch removal in all animals and 24 hours after patch removal in 2 animals. This was said to make readings for erythema impossible. No erythema was observed in any animal at the possible reading times, and no oedema was present. Body weights were normal and no other clinical symptoms were observed.

IRGAZIN DPP Orange 16AOA was concluded to be a non-irritant to the skin of rabbitsunder the conditions of this study.

9.1.4 Eye Irritation (6)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 405.*

New Zealand White rabbits (three males) were administered a single dose of 0.1 ml (0.22 mg) IRGAZIN DPP Orange 16AOA in a 17% w/w water suspension into the conjunctival sac of the left eye. The other eye remained untreated and was used as a control. Animals were observed at 1, 24, 48 and 72 hours and 7 and 14 days after administration of the test substance.

Slight redness of the conjunctivae was present in two animals and persisted for 24 hours. Slight swelling was present in one animal at one hour only. The third animal showed no symptoms.

No clinical signs of systemic toxicity were observed.

IRGAZIN DPP Orange 16AOA was concluded to be a slight irritant to the eye of the rabbit under the conditions of the study.

9.1.5 Skin Sensitisation (7)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 406*.

The test used was the guinea-pig maximisation test of Magnusson and Kligman (ref).

From a pretest using four animals, an intradermal concentration of 5% IRGAZIN DPP Orange 16AOA in oleum arachidis was selected for the main study.

An epidermal concentration of 50% in vaseline was selected for the main study after testing the four animals with 10 and 20, or 30 and 50% IRGAZIN DPP Orange 16AOA in vaseline on each of the right and left flanks.

Induction Study

Thirty guinea-pigs (15 of each sex) of the Pirbright White strain (20 test and 10 control animals) were used.

On day one three pairs of intra-dermal injections (0.1 ml) were made into the clipped scapular region of each test group guinea-pig. The injected solutions were:

Freund's Complete Adjuvant with physiological saline (50:50 v/v).
IRGAZIN DPP Orange 16AOA diluted to 5% with Oleum arachidis w/v.
IRGAZIN DPP Orange 16AOA diluted to 5% in a 50:50 adjuvant/saline mixture.

Control animals received only Freund's Complete Adjuvant with physiological saline (50:50 v/v) and undiluted Oleum arachidis.

On day 7 the application site was treated with 10% sodiumlaurylsulfate, to induce a mild inflammatory response. On day 8 the areas of the injection sites were treated with an occlusive epidermal application of 50% IRGAZIN DPP Orange 16AOA in vaseline. The bandage remained in place for 48 hours. Patches contained 0.4 g of test substance over an area of 4 x 4 cm. Control animals were similarly treated but without the use of the test substance. The sites were evaluated 24 and 48 hours after removal of the bandages.

Challenge Study

Two weeks after the epidermal induction application, the test and control animals were challenged topically with IRGAZIN DPP Orange 16AOA. Filter paper was saturated with 50% w/w of IRGAZIN DPP Orange 16AOA or with vaseline vehicle only. The test substance was applied to one flank of each guinea-pig and the vaseline to the other flank. Patches contained 0.2 g of test substance over an area of 2 x 2 cm. The bandages remained in place for 24 hours and assessment was made of the skin reactions at 24 and 48 hours after removal of the bandages.

A second challenge was performed one week after the first challenge, because several control animals had presented with skin reactions. Four control animals and eight test animals had exhibited slight erythema and oedema 48 hours after bandage removal. Test and control animals were treated with 30% IRGAZIN DPP Orange 16AOA in vaseline or vaseline only on the two flanks, as described above. New control animals were used for this second study.

No animals in the second challenge were sensitised by the test substance. Body weights were not affected during the study and no toxic symptoms were observed in any animals.

IRGAZIN DPP Orange 16AOA was considered not to be a skin sensitiser in guinea-pigs.

9.2 Repeated Dose Toxicity (8)

Groups of 10 rats (5 of each sex) of a Wistar-derived strain were treated orally by gavage, once daily, 7 days a week for 4 weeks. Animals received 0, 50, 200 or 1000 mg/kg/day of IRGAZIN DPP Orange 16AOA dissolved in corn oil at 10 ml/kg. Animals were necropsied after the 28-day treatment period was over. In a recovery study 5 animals of each sex were treated with 0 or 1000 mg/kg and allowed a 14 day recovery period prior to necropsy being performed.

Body weights, food consumption and organ weights of treated animals varied slightly but this could not be attributed to treatment. No treatment-related deaths, clinical signs or changes in ophthalmic properties were observed among any treatment group. No changes of toxicological significance occurred in animals of either sex to haematological parameters or clinical biochemistry parameters; all changes were considered to be within the normal range of variation for animals of this strain and age.

All animals of the high treatment group produced red faeces from the second or third day of treatment to the first or second day of the recovery period. Macroscopic changes observed included dilated renal pelves, reddish discolouration of various organs and dilated uterine horns. These findings were observed in all four groups and during the recovery period. They did not appear to be related to the treatment level in their incident rate. Discolouration of the gastrointestinal tract was concluded to be due to the passive colouration of the treatment article, as confirmed by red particulate matter in the gastrointestinal tract of some animals observed in microscopic examination. No other microscopic observations were made that could be attributed to treatment.

In conclusion, no toxicologically significant changes were observed in any animals treated with up to and including 1000 mg/kg/day of IRGAZIN DPP Orange 16AOA.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium and Escherichia coli Reverse Mutation Assay (9)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 471.*

IRGAZIN DPP Orange 16AOA was tested in the reverse mutation assay on *S. typhimurium* strains TA98, TA100, TA1535 and TA1537, and *E. coli* strain WP2*uvrA* in the presence or absence of rat liver microsomal S9 activation.

As a result of a preliminary study the concentrations selected for the main study were 0, 33.3, 100.0, 333.3, 1000, 2500 and 5000 µg IRGAZIN DPP Orange 16AOA/plate dissolved in dimethylsulfoxide. Toxicity was not evident up to the maximum tested 5000 µg/plate. Positive controls used in the absence of S9 activation were 4-nitro-o-phenylenediamine, sodium azide, and 2-nitrofluorene, 9(5)-aminoacridine and 4-nitroquinoline-N-oxide. 2-aminoanthracene and cyclophosphamide were used as the positive controls in experiments including rat liver S9 mix.

No significant, dose-dependent increases in the number of revertant colonies of bacteria were recorded for any of the bacterial strains with or without activation. All positive control substances produced marked increases in the number of revertant colonies within the anticipated range.

In conclusion, under the conditions of this experiment, IRGAZIN DPP Orange 16AOA was not found to be mutagenic to either *Salmonella typhimurium* or *Escherichia coli*.

9.3.2 Chromosomal Aberrations in Chinese Hamster Ovary Cells (10)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 473*.

IRGAZIN DPP Orange 16AOA was investigated for its potential to cause chromosomal aberrations *in vitro* in the V79 line of cells from the Chinese hamster.

Preliminary experiments were performed in order to determine the toxicity of IRGAZIN DPP Orange 16AOA to the cells. Cytotoxicity was not observed up to the maximum concentration used of 5000 ng/ml. The culture medium and solvent (DMSO) were used as the negative controls; ethylmethanesulfonate (4.8 mM final concentration) and cyclophosphamide (1.7 µM final concentration) dissolved in nutrient medium were the positive controls utilised.

Two experiments were performed using cultures in the presence and absence of S9 metabolic activation. A single cell suspension of V79 was prepared from 3 or 4 day-old exponentially growing stock. Cells were subsequently treated with IRGAZIN DPP Orange 16AOA for 4 hs with metabolic activation or 18 h or 28 h without metabolic activation. Chromosomes were prepared 18 h or 28 h after treatment. Concentrations of IRGAZIN DPP Orange 16AOA used were 300, 3000 and 5000 ng/ml for the 18 h fixation interval and 5000 ng/ml for the
28 h fixation interval. Precipitation of the test article occurred at 5000 ng/ml both with and without S9 mix thus limiting the concentrations available.

The mitotic indices were not reduced significantly after treatment with the highest dose (5000 ng/ml) in either the presence or absence of S9. No increases in the rate of polyploid metaphases were observed compared to controls. The chromosomal aberration rates of treated cells were found not to be significantly higher than the corresponding control values.

In conclusion, IRGAZIN DPP Orange 16AOA was found not to be a clastogen in the V79 Chinese hamster cell line under the conditions of the study.

9.4 Overall Assessment of Toxicological Data

IRGAZIN DPP Orange 16AOA was found to be of low acute toxicity to the rat. The acute oral and dermal LD_{50}s were both > 2000 mg/kg. The substance was found to be non-irritating to the skin and a mild irritant to the eye of the rabbit. It was non-sensitising to the skin of the guinea-pig. A 28 day feeding study showed no results of toxicological significance when animals were treated with IRGAZIN DPP Orange 16AOA at up to and including 1000 mg/kg/day. Colouration of the intestinal tract and faeces due to passive colouration from the test article was the only notable observed effect. IRGAZIN DPP Orange 16AOA was found to be non-mutagenic to both *Salmonella typhimurium* and *Escherichia coli* and found not to induce structural chromosomal aberrations in the V79 Chinese hamster cell line *in vitro*.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

All ecotoxicity tests were conducted according to Good Laboratory Practice procedures. An auxiliary emulsifier TWEEN 80 was added to the test solutions for each of the tests, in an attempt to improve the solubility of the test substance. However, it is unclear whether the substance was in solution at all concentrations during these tests.

Species	Test (Ref)	Guideline	Result
Rainbow Trout *Oncorhynchus mykiss*[1]	Acute Toxicity (96 h) Semi-static conditions (11)	EEC Directive 92/69, Annex V, C.1 : OECD Guideline 203	LC_{50} > 40 mg/L
Daphnia magna[2]	Acute Toxicity (24 and 28 h) (12)	EEC Directive 92/69, Annex V, C.2	EC_{50} > 40 mg/L NOEC > 40 mg/L
Scenedesmus subspicatus[3]	Growth Inhibition (72 hour) (13)	EEC Directive 92/69, Part C.3, OECD Guideline 201	NOEC (growth) > 40 g/L NOEC (biomass) > 40 g/L EbC_{50} > 40 mg/L ErC_{50} > 40 mg/L
Waste-water Bacteria[4]	Respiration Inhibition Test (14)	EEC Directive 87/302, Part C, Public.. No. L133/118 OECD Guideline	EC_{50} > 100 mg/L

Footnotes to Table 2

1. A loss in concentration of the test substance of 2.2 - 4.4 % was noted over the test period. Colouration of the test solution by the pigment meant that the test fish had to be moved to control water for observation at the end of the test.

2. No loss of test article was noted over time.

3. Test concentrations used were 0.4, 1.3, 4.0, 12.6 and 40 mg/L. Growth inhibition up to 23% in test solutions was thought to be due to the loss of light in the test media, due to colouration by the pigment. A 10% loss of concentration of the test substance was noted over the test period.

4. Test suspensions (containing Tween-80 at 0.01%) used were 3.2, 10, 32, 50 and 100 mg/L. Inhibition rates ranged from 4.9% to 16.4%.

These results appear to indicate that the substance is not toxic up to the solubility limit to the range of organisms tested. Due to the colouration of the test media, assessment of the inhibition effects on test species would be difficult to observe.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The main disposal route for the notified substance will be to landfill. The following calculations have been based on an annual production level of new vehicles in Australia of 500,000 (15) , and on the current levels of orange pigment used in cars (an estimated 5% of all new cars produced, based on advice from the notifier), and assumes no incineration disposal of wastes. Thus a total of 2,500 new cars may be painted orange each year. In addition, an estimated 10% of all cars produced using the pigment may require repair/respraying (ie 2,500 cars), and 2% may be dumped/wrecked each year (ie. 500 cars).

Total wastes to landfill will thus be 750 kg (new vehicles), 125 kg (repaired vehicles) and 100 kg (dumped/wrecked vehicles), totalling approximately 1 tonne each year.

As a result of using the pigment in paints, plastics, inks and masterbatch operations, total wastes passing to waterways are estimated to be less than 5 kg per year. These wastes are expected to be disposed of in a very dispersed manner throughout the entire year.

The majority of the pigment will be disposed of to landfill (where it is expected to remain, given the low solubility of the substance) and the remainder disposed of in a dispersed manner in very small quantities throughout the year. These factors combined with the low toxicity to aquatic organisms and the pigments low fat solubility, suggest that the notified substance will not present a significant environmental hazard.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

IRGAZIN DPP Orange 16AOA is a powder with a partition coefficient log P_{OW} of 5, low fat solubility (< 0.0002 g/100g) and low water solubility (< 0.0001 g/L). Although the partition coefficient implies that bioaccumulation is possible, the low fat and water solubility data suggest that this is unlikely. The notified substance has a negligible vapour pressure and > 99.9% of the particles are less than 2 μm diameter and therefore well within the respirable range of less than 10 μm.

IRGAZIN DPP Orange 16AOA is likely to be of low oral and dermal toxicity in humans and to be non-irritating or very slightly irritating to the eyes and skin. It may cause lung irritation due to its particle size.

Exposure to the notified chemical is possible via the lungs, skin or eye contact. Aerosol generation and subsequent exposure is possible during weighing and transferring processes. The use of whole bags of chemical and local exhaust ventilation will reduce the potential for exposure. After mixing, exposure potential will be much reduced as the IRGAZIN DPP Orange 16AOA has been much diluted and is in liquid formulation. The mixing processes are normally performed in sealed vessels. Methods used to control exposure to solvents during the application processes are expected to be adequate to control against the unknown hazards of the polymer.

The masterbatch (paint concentrate) process is performed in sealed mixers and results in the pigment becoming encapsulated for use in plastics. Exposure to the pigment will not occur after encapsulation. End users such as painters and printers will be exposed to the pigment only after its formulation with resins, varnishes, solvents or oils. Exposure will then be largely dermal and at low concentrations.

In conclusion, when used under the conditions described by the notifier IRGAZIN DPP Orange 16AOA presents a low risk to those working with the chemical and to the general public.

13. RECOMMENDATIONS

To minimise occupational exposure to IRGAZIN DPP Orange 16AOA the following guidelines and precautions should be observed:

. If engineering controls and work practices are insufficient to reduce exposure to IRGAZIN DPP Orange 16AOA to a safe level, the following personal protective equipment should be used:

– respiratory protection conforming to Australian Standards AS 1715 (16) and AS 1716 (17);

– chemical-type goggles conforming to Australian Standards AS 1336 (18) and 1337 (19);

– impervious gloves conforming to Australian Standards AS 2161 (20); and

– overalls.

. good work practices should be implemented to avoid generation of dust and liquid spills.

. spills should be cleaned up promptly.

. good personal hygiene practices should be observed.

. a copy of the Material Safety Data Sheet (MSDS) for IRGAZIN DPP Orange 16AOA and products containing it should be easily accessible to all employees.

14. MATERIAL SAFETY DATA SHEET

The attached MSDS for IRGAZIN DPP Orange 16AOA was provided in Worksafe Australia format (21).

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. 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 16AOA shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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