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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

PF-310

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989, as amended* 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 Arts, Sport, the Environment and Territories and the assessment of public health is conducted by the Department of Health, Housing and Community Services.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

PF-310

1. APPLICANT

Inchcape Office Products Pty Ltd, 12 Barcoo Street, East Roseville NSW 2069

2. IDENTITY OF THE CHEMICAL

Based on the final concentration of the notified chemical in the imported product, PF-310 is not considered to be hazardous. Therefore the chemical name, CAS number, structural and molecular formulae, molecular weight, spectral data, specific use and the import volume have been exempted from publication in the Full Public Report and Summary Report.

Other name:	PF-310 FT-310
Trade name(s):	Ricoh FT Black Toner Type 8800
Molecular weight:	<1000

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Light yellow powder
Odour:	No appreciable odour
Melting Point:	> 400°C
Density:	1780 kg/m^3{for density}
Vapour Pressure:	0.012 kPa at 25°C
Water Solubility:	0.25 g/L at 20°C
Fat Solubility:	1.19 mg/100g of standard fat HB 307 at 37°C

Partition Co-efficient (n-octanol/water) log $P_{O/W}$:	2.3 (estimated)
Hydrolysis as a function of pH:	At pH 7 the chemical is hydrolytically stable. At pH 4 and 9 after 144 hrs concentration is decreased by about 30%
Adsorption/Desorption:	Not provided
Dissociation Constant	pKa of 4.08 at 20°C
Flash Point:	Could not be ignited
Flammability Limits:	Not flammable
Decomposition Temperature:	> 180°C
Autoignition Temperature:	Not auto-flammable
Explosive Properties:	Not explosive under the influence of flame, shock or friction
Reactivity:	Has no oxidising properties
Particle size:	Not provided

Comments on Physico-Chemical Properties:

Melting point could not be determined exactly under the conditions of the test, but did not occur under 400°C. A colour change and loss of weight at above 180°C, which persisted after cooling, suggested decomposition of the substance at temperatures above 180°C.

The vapour pressure indicates that the substance is relatively volatile for an organic salt. However, the vapour pressure was difficult to determine accurately, due to the changing composition of the vapour during the test procedure, as a volatile impurity was removed gradually.

Observations during the test indicate that the substance is surface active, and therefore the partition co-efficient value is difficult to interpret.

Adsorption/desorption details were not provided, which is acceptable given the low importation volume and method of use of the chemical. However, if greater quantities are to be imported in the future, leading to more significant environmental exposure, this information should be provided. This is of concern given the soluble nature of the chemical, low biodegradability, and the low partition co-efficient - all of which mean that the chemical could be mobile if it were to become incorporated into the soil compartment. The substance will hydrolyse in both acidic and alkaline conditions.

4. PURITY OF THE CHEMICAL

Degree of purity: 99.2% (99.0%-99.9%)

Toxic or hazardous impurity/impurities: None known

Non-hazardous impurity/impurities (> 1% by weight): None

Additives/Adjuvants: None

5. INDUSTRIAL USE

The chemical is to be used as a photocopier toner additive. The estimated import volume is to be less than 1 tonne per year.

6. OCCUPATIONAL EXPOSURE

PF-310 will not be manufactured in Australia. The chemical will be imported as an ingredient of a formulated product in 1-2 kg ready to sell packages. The formulated product contains less than 1% of PF-310. Any risk of worker exposure during storage and transport is unlikely.

Workers likely to be exposed to PF-310 are:

. photocopier service engineers involved in the installation and maintenance of dry process photocopiers. Approximately

50-60 service engineers will be involved in these tasks in Australia and will be servicing many machines on a daily basis; and

. office workers who add toner to photocopiers *in situ* including workers involved in full time photocopying and machine upkeep.

The number and categories of workers exposed to the product in Australia will be large depending on the number of machines used and the amount of photocopying carried out on each machine. The product containing the chemical is in a cartridge thus minimising direct contact with the notified chemical.

7. PUBLIC EXPOSURE

The potential for public exposure to PF-310 is anticipated to be low. The notified chemical will be contained in a cartridge and public exposure will arise through contact with dust particles during maintenance of the photocopiers or through contact with residues on photocopied paper. These are not regarded to be significant as in most cases (except for people employed for photocopying) the process of photocopying is carried out infrequently and the packaging of the product in cartridges will markedly reduce exposure potential.

The notified chemical and products containing the notified chemical will be disposed of as domestic waste.

8. ENVIRONMENTAL EXPOSURE

. Release

As all formulation and packaging will be carried out overseas, no environmental exposure is expected in Australia from these processes.

Toner is added to photocopiers as required. The contents of the entire packet is added to the machine, and the empty toner container is discarded. The product, its containers and materials contaminated with the chemical can be disposed of as domestic waste to landfill in accordance with local, State and Federal regulations. Waste materials from products containing

PF-310 should not be burnt, owing to the presence of halogen atoms.

Releases to the environment may occur through processing of waste paper. This possibility is explored further below.

. **Fate**

The chemical is likely to arrive in a dispersed manner in landfill bound to waste paper. As such, it may biodegrade slowly when placed in the landfill.

Paper recycling is a growing industry in Australia. Wastepaper is repulped using a variety of alkalis, dispersing agents, wetting agents, water emulsifiable organic solvents and bleaching agents. These chemicals enhance fibre separation, ink detachment from the fibres, pulp brightness and whiteness of the paper. After pulping, the contaminants and the ink are separated from the fibres by pumping the stock through various heat, washing, screening, cleaning, flotation and dispersion stages. The notifier has provided no data on the likely behaviour of the chemical during the recycling process. The chemical may survive the above conditions, either remaining bound to the pulp or becoming associated with the sludge. In the latter case, the chemical may arrive in landfill, where it would be subject to low biodegradation. However, given the soluble nature of the chemical, it is likely to remain longer in the aquatic compartment.

When subjected to a modified Sturm test (OECD No 301B), biodegradation occurred at 10 mg. L^{-1} (20%) and 20 mg. L^{-1} (35%) over a 28 day period, which means that the product is not readily biodegradable.

No bioaccumulation data was provided on the grounds that "if the substance is readily biodegraded, this data does not have to be supplied". Although PF-310 does not appear to be readily biodegradable, the small quantities to be imported and the relatively high water solubility mean that this information is not required.

9. EVALUATION OF TOXICOLOGICAL DATA

Under the *Industrial Chemicals (Notification and Assessment) Act, 1989* toxicity data are not required for chemicals manufactured or imported in volumes less than 1 tonne/year. However, the following studies were provided and have been assessed.

9.1 Acute Toxicity

Table 1: Summary of the acute toxicity of PF-310.

Test	Species	Outcome	Reference
Oral	Rat	LD50 > 5000 mg/kg	(1)
Dermal	Rat	LD50 > 2000 mg/kg	(2)
Skin Irritation	Rabbit	Non-irritant	(3)
Eye Irritation	Rabbit	Corrosive	(4)
Skin Sensitisation	Guinea Pig	Non-sensitising	(5)

9.1.1 Oral Toxicity (1)

This study was carried out according to *OECD Guidelines for Testing of Chemicals No: 401*.

Ten albino Wistar strain rats, 5 male and 5 female, were selected for the study. PF-310 (99.2%) was administered by gavage at a purity of 99.2%. The animals received a dose of 5000 mg/kg. They were observed for gross toxicological effects at periodic intervals on the day of dosing and once daily thereafter for 14 days. All animals surviving to the end of the period were sacrificed and necropsied.

No mortality occurred during the study period. Rough coat was observed in all males. No other signs of toxicity were observed.

All the rats had gained weight by day 14. Macroscopic examination at necropsy did not reveal any abnormalities due to PF-310.

The results of this study indicate that PF-310 has an oral LD50 > 5000 mg/kg.

9.1.2 Dermal Toxicity (2)

This study was carried out in accordance with *OECD Guidelines for Testing of Chemicals No: 402*.

A single dose of 2000 mg/kg of PF-310 was administered by occlusive application to the shaved backs of 10 albino rats Wistar strain (5 male and 5 female) for 24 hours. The animals were observed for 14 days and the surviving rats were sacrificed and subjected to necropsy.

There were no deaths during the study. A gain in body weight was noted for all animals. Lethargy was observed in three males on days 1 and 2. No other toxic signs related to the chemical were noted. Erythema was observed at the site of application in two female rats from day 5 onwards. One of these females showed scales on the treated area between days 7 and 9. Macroscopic examination of the animals at post-mortem did not reveal any abnormalities.

The results of this study indicate that the dermal LD50 for PF-310 is >2000 mg/kg.

9.1.3 Skin Irritation (3)

The study was carried out in accordance with the *OECD Guidelines for Testing of Chemicals No 404.*

A single dose of 0.5 gm of PF-310 was administered by occlusive application to the intact skin of a shaved area on one flank of three New Zealand strain albino rabbits. The other flank was similarly prepared to act as a procedural control. Patches were applied to the unabraded area of the skin for four hours. The site of application was observed at approximately 60 mins, 24, 48 and 72 hours after removal of the patch.

Yellow staining of the treated skin by the test substance was observed. Very slight erythema was observed in 2/10 animals and slight oedema in one animal at the end of 60 mins. The skin irritation was reversed within 24 hours after exposure in all three animals. No symptoms of systemic toxicity were observed in the animals during the test period and no mortality occurred.

The results of this test indicate that PF-310 is not a skin irritant.

9.1.4 Eye Irritation (4)

The test was conducted in accordance with *OECD Guidelines for Testing of Chemicals No 405*

One hundred milligrams of PF-310 was instilled into the conjunctival sac of one eye of three New Zealand strain albino rabbits. The other eye served as the control. The eyes of each animal were examined 1, 24, 48 and 72 hours and 7, 14 and 21 days after instillation of the test substance. After the 24 hr observation a solution of 2% fluorescein was instilled into both eyes to quantitatively determine corneal epithelial damage. This procedure was repeated in all the animals on days 4, 8, 15 and 22. At the end of 1 hr congestion, swelling and circumcorneal hyperaemia were observed in the iris of all three rabbits. PF-310 also caused redness and chemosis of the conjunctivae of the three rabbits. The injection of the iris was reversed within 21 days after instillation in 2/3 rabbits. The three animals showed translucent corneal opacity and neovascularisation, diffuse beefy redness of the conjunctivae and some discharge on day 22. Treatment of the eyes with 2% fluorescein revealed corneal epithelial damage in all three animals. No systemic symptoms were observed in the animals and no mortality occurred.

The results of this test indicate that PF-310 is corrosive to the eye.

9.1.5 Skin Sensitisation (5)

This study was carried out in accordance with the *OECD Guidelines for the Testing of Chemicals No 406.*

The test used was the guinea-pig maximisation test of Magnusson and Kligman. The skin reactions were assessed according to a four point scale. The sensitivity of the guinea-pig strain used was checked periodically with formaldehyde.

Preliminary Study

To determine the dose level for intradermal injection in the main study, four injections were made into the clipped shoulder region of one female albino guinea pig of the Himalayan strain at a concentration of 5% in distilled water. The dermal reactions were assessed 24 and 48 hours later.
Moderate erythema around a necrotic area was observed at the end of 24 hours. A concentration of 2.5% in physiological saline was then apparently arbitrarily used as the inducing dose in the main study.

To determine the dose level for topical induction in the main study, four animals were topically treated with 0.5 ml of a 50%, 25%, 10% and 5% concentration of PF-310 in distilled water by occlusive application. This procedure ensured intensive contact of PF-310 even though it is insoluble in the vehicle used. The reaction sites were assessed 24 and 48 hours after bandage removal. No erythema or necrosis was observed at the end of 24 or 48 hours.

The dose level selected for topical challenge in the main study was 50% w/w in distilled water.

Induction and Challenge Study

Induction

Thirty female albino guinea-pigs of the Himalayan strain (20 test and 10 control animals) were used.

Three pairs of intra-dermal injections were made into the clipped scapular region of the guinea-pig. The injected solutions were: PF-310 dissolved to 2.5% w/w with physiological saline, Freund's Complete Adjuvant 50:50 with distilled water for and 5% concentration of PF-310 emulsified in a 50:50 mixture of Freund's Complete Adjuvant. Seven days after the intra-dermal injections and prior to the epidermal application of PF-310 the intra-

scapular area was treated with 10% Sodium-Dodecyl Sulphate (SDS) in petrolatum. This concentration of SDS enhances sensitisation by provoking a mild inflammatory reaction. Seven days after the SDS treatment 0.5 ml of a 50% solution of PF-310 was applied to the same region. The residual chemical was removed at the end of 48 hrs and reaction sites were assessed for erythema and oedema.

The animals in the control group were treated by epidermal and intradermal inductions with the omission of PF-310.

After induction, 11/20 animals showed well defined erythema while 9/20 had slight erythema after 48 hrs, in the group receiving PF-310. Slight oedema was also observed in 8/20 animals.

Challenge

Two weeks after the topical induction application the test and control animals were challenged topically using 0.5 ml of PF-310 at concentrations of 50%, 25% and 10% in distilled water and distilled water by occlusive application. The challenge sites were evaluated 24 and 48 hours after removal of the patches.

No skin reactions were seen in the control group after challenge exposure. In the experimental group 4/20 animals receiving 50% w/w PF-310 developed mild erythema. No reactions were seen in the animals receiving 25% and 10% concentrations of PF-310 and distilled water. No symptoms of systemic toxicity or mortality were observed in the animals during the study.

In the case of adjuvant-type test, an erythema response in at least 30% of the treated animals is considered to be positive. Therefore, the results of this study indicate that PF-310 is not a skin sensitiser at the highest concentration tested.

9.2 Repeated Dose Toxicity (6)

This study was carried out according to *OECD Guidelines for Testing of Chemicals No: 407*

A five day range finding study was performed with 3 rats/sex/group at dose levels of 50, 200 or 1000 mg/kg to provide a basis for selection of dose levels. No effects were observed at the highest dose, therefore, a high dose level of 1000 mg/kg/day was selected for a study of 28 days duration.

PF-310 in distilled water was administered by gavage, once daily, at doses of 50, 200 or 1000 mg/kg to groups of five male and five female SPF-bred Wistar rats. The animals were treated for 28 days. The control group consisted of five male and five female rats and received only distilled water. Body weights, food and water consumption and clinical observations were recorded. Blood samples were taken on day 28. Surviving animals were killed and examined macroscopically. Microscopic examination of the tissues was also carried out.

In rats receiving 1000 mg/kg of PF-310, a swollen appearance of the abdomen was seen in all animals from week 3 of treatment till termination. Two males and one female rat developed rales and laboured breathing. Excessive salivation was also noted in more than 75% of the animals receiving this dose. The body weights and food consumption of animals in this group were lower than controls over the four week treatment period.

In rats dosed with 200 mg/kg, excessive salivation was seen in 25% of the animals from day 9 onwards. Rales and laboured breathing was noted in one male and one female.

No toxic effects related to the chemical were noted in animals receiving 50 mg/kg. Body weights and food consumption of animals receiving 200 or 50 mg/kg were similar to control body weights.

Haematological and clinical parameters of treated rats did not show any difference from those of control rats.

Macroscopic examination at necropsy showed enlargement of the caecum, colon or the whole gastro-intestinal tract in all animals receiving 1000 mg/kg. Other findings in this group were pale kidneys, alopecia and a grey-white nodule in the fore-stomach. These were noted incidentally and not considered to exceed normal incidences of background variation. Absolute and relative organ weights of treated animals were in the same range as controls.

Rats dosed at 1000 mg/kg with enlarged caecums showed no histopathological lesions, however, one male rat had an inflammatory reaction in the caecum and colon. No microscopic changes were seen in animals receiving 200 or 50 mg/kg.

Enlarged gastro-intestinal areas could be attributed to gas accumulation and may be indicative of local or diffuse gastro-intestinal paralysis or change in the gut flora.

These data indicate that the gastro-intestinal tract is the target organ for toxicity of PF-310 with repeated oral doses in rats.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (7)

This study was carried out according to the *OECD Guidelines for Testing Chemicals No 471.*

A preliminary toxicity test with strain TA 100 was carried out, both with and without S9-mix, for selection of a range of doses. The doses used were 1, 3.3, 10, 33.3, 100, 333, 1000, 3330, 5000 µg/plate. The doses selected for the main study were 1, 3.3, 10, 33.3 and 100 µg/plate. *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100, both in the presence and absence of S9-mix were used. Positive controls used were sodium azide, 9-aminoacridine, daunomycin and methylmethanesulfonate. 2-Aminoanthracene was used as a positive control in experiments using S9.

In the experiment, the test substance did not induce an increase in the revertant colony numbers per plate at any concentration tested with or without metabolic activation.

The results of this study indicate that PF-310 is not genotoxic towards *Salmonella typhimurium.*

9.3.2 Analysis of Metaphase Chromosomes (8).

This study was carried out according to the *OECD Guidelines for Testing Chemicals No 473.*

Cultured human lymphocytes were exposed to 10, 33, 100 and 333 µg/ml of PF-310 for 2 hrs with or without S9 mix. After 2 hr treatment the cells were rinsed and incubated for 21-23 hrs or 45-47 hrs. Mitotic activity was arrested by the addition of colchicine to the culture three hours before the end of the

incubation. Mitomycin C 0.5 µg/ml and cyclophosphamide 15 µg/ml were used as positive controls. Cells were fixed, stained and examined for clastogenicity.

Both in the presence and absence of S9-mix, PF-310 did not induce an increase in the number of cells with chromosome aberrations

The results of this study indicate that PF-310 is not clastogenic towards cultured human lymphocytes.

9.4 Overall Assessment of Toxicological Data

PF-310 has a low acute oral toxicity with an oral LD_{50} in the rat >5000 mg/kg. It also has a low acute dermal toxicity in rats (LD50 in rats >2000 mg/kg). PF-310 is not a skin irritant but is corrosive to the eye. It was found not to cause skin sensitisation at a concentration of 50%. PF-310 was not mutagenic towards *Salmonella typhimurium* and did not cause chromosomal aberrations *in vitro* in human lymphocytes.

In the 28 day repeated oral dose study in rats, PF-310 administration was associated with swollen appearance of the abdominal area, rales, laboured breathing and excessive salivation at 1000 mg/kg/day. There were no significant haematological changes. The target organ for toxicity was the gastro-intestinal tract.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Information has been submitted on ecotoxicology data, and whilst not required for this type of notification, has been summarised below.

Toxicological analyses were conducted in accordance with OECD and EEC guidelines in all cases, using static and semi-static conditions. The fish results are based on measured concentrations taken at the end of the test period, while the acute Daphnia results are based on nominal concentrations. By contrast, the measured concentration in the chronic Daphnia test has decreased significantly in the 48 hour renewal period.

• Aquatic Toxicity

Test	Species	Results
24 hour exposure	Carp	LC50 = 2.4 mg/L
96 hour exposure	Carp	LC50 = 1.9 mg/L
24 hour exposure	Daphnia	EC50 = 7.9 mg/L
48 hour exposure	Daphnia	EC50 = 4.4 mg/L
21 days Immobilisation	Daphnia	NOEL = 3.3 mg/L
"	Daphnia	EC50 = 1.0<X<3.2 mg/L
Reproduction	Daphnia	EC50 = 1.0<X<3.2 mg/L
"	Daphnia	LOEC = 1.0 mg/L
"	Daphnia	NOEC = 0.32 mg/L

• Other Non-Target Invertebrates

Test	Species	Results
Acute Static (14 day)	Earthworm	LC50 > 1000 mg/kg

The above results indicate that the chemical is moderately toxic to aquatic organisms, but practically non-toxic to earthworms.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The low environmental exposure of the chemical as a result of normal use indicates that the overall environmental hazard should be negligible.

Spillage during transport or disposal of spilt material in landfills should represent very minor risk to the environment, as the concentration of PF-310 in the imported product is so low. Accidental spillage of the chemical should result in negligible hazard as it will be marketed in small packages (cartridges) for direct filling into photocopier machines.

Environmental exposure to the notified substance could occur when paper containing the chemical is recycled or disposed of. Exposure of the aquatic compartment to effluents resulting from paper recycling could potentially occur, due to the relatively high water solubility of the chemical and its resistance to biodegradation. The moderate toxicity of this chemical to fish and other aquatic organisms would thus be of concern. However,

the very small proportion of this chemical in the formulated product should mean that this risk will again be minimal, due to the expected very low environmental concentrations.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

PF-310 will be imported in low volumes as an ingredient (<1% concentration) in a formulated product. The main occupational exposure to PF-310 is likely to be by skin and eye contact. Based on the results of the animal studies, the notified chemical has a low acute oral and dermal toxicity. PF-310 is not a skin irritant but is corrosive to the eye when tested in an undiluted form. However, as the notified chemical is imported as a minor constituent of a formulated product, it is not expected to be a risk to human health.

Public exposure to the notified chemical is expected to be minimal as the product is contained in a cartridge.

13. RECOMMENDATIONS

To minimise occupational exposure to PF-310 the following guidelines and precautions should be observed:

. Workers who frequently come into direct contact with the toner powder should avoid skin contact with the powder;

. Dust generation should be avoided while adding toner to photocopiers and during maintenance;

. Good work practices should be implemented to avoid spillages;

. Good personal hygiene should be observed; and

. A copy of the MSDS for products containing PF-310 should be made easily accessible to workers.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for product containing PF-310 (Attachment 1) was provided in Worksafe Australia format (9). The MSDS was provided by Inchcape Office Products Pty 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 Inchcape Office Products Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of PF-310 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

1. Assessment of Acute Oral Toxicity with PF-310 (FT-310) in the Rat. Data on file. RCC NOTOX Project 055722, 1991.

2. Assessment of Acute Dermal Toxicity with PF-310 (FT-310) in the Rat. Data on file. RCC NOTOX Project 055733, 1991.

3. Primary Skin Irritation/Corrosion Study with PF-310 (FT-310) in the Rabbit (4-Hour Semi-Occlusive Application). Data on file. RCC NOTOX Project 055744, 1991.

4. Acute Eye Irritation/Corrosion Study with PF-310 (FT-310) in the Rabbit. Data on file. RCC NOTOX Project 055755, 1991.

5. Assessment of Contact Hypersensitivity to PF-310 (FT-310) in the Albino Guinea Pig (Maximization Test). Data on file. RCC NOTOX Project 055766, 1991.

6. Subacute 28-Day Oral Toxicity with PF-310 (FT-310) by Daily Gavage in the Rat. Data on file. RCC NOTOX Project, 1991.

7. Evaluation of the Mutagenic Activity of PF-310 (FT-310) in the Ames Salmonella/Microsome Test (With Independent Repeat). Data on file. RCC NOTOX Project 055799, 1991.

8. Evaluation of the Ability of PF-310 (FT-310) to Induce Chromosome Aberrations in Cultured Peripheral Human Lymphocytes. Data on file. RCC NOTOX 055801, 1991.
9. National Occupational Health and Safety Commission, *Guidance Note for the Completion of a Material Safety Data Sheet*, 2nd edition, AGPS, Canberra, 1990.