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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

FPC-156

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

FPC-156

1. APPLICANT

Collie Cooke Limited, Cnr Gracie and Reynolds Sts, North Melbourne, Victoria, 3051.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, FPC-156 is not considered to be hazardous. Therefore, the chemical name, other names, CAS registry number, molecular formula, structural formula, molecular weight, method of detection and determination and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Trade name: FPC-156

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20C and 101.3 kPa:	white poowder
Melting Point/Boiling Point:	not determinable, decomposes at 295 ^{0}C prior to melting
Relative Density:	1400 kg/m^3
Vapour Pressure:	3.1 x 10^{-14} kPa at 25^{0}C
Surface Tension:	72.0 mN/m at 0.18 g/L (saturated)
Water Solubility:	0.17 g/L @ 20^{0}C

Fat Solubility:	10.7 mg/100g fat
Partition Co-efficient (n-octanol/water) log $P_{o/w}$	0.936
Hydrolysis as a function of pH:	hydrolysis rate constant: k(h) = 0.00210 @ pH 9 and 25 ^{0}C; Environmental Half-life: $te_{1/2}$ = 329 hours
Dissociation Constant:	does not dissociate in water
Flash Point:	not determined as the method indicated is applicable to liquids only
Autoignition Temperature:	no ignition was observed below 400^{0}C
Explosive Properties:	non-explosive
Reactivity/Stability:	shown to be oxidising (EEC method A17)

Missing data on adsorption/desorption is acceptable as the quantity of chemical to be imported is <1000 kg per annum and this test is not required in the European Community for such quantities. Data on particle size distribution were not provided as the notified chemical will not be available in powder form in Australia.

4. PURITY OF THE CHEMICAL

Degree of purity: >99.9%

Toxic or hazardous impurities: none

Non-hazardous impurities: none

5. INDUSTRIAL USE

FPC-156 will be imported into Australia as a component of lithographic film developer. The film developer will contain <1 w/w% of the notified chemical. Less than 10 kg of the notified chemical will be imported per annum.

6. OCCUPATIONAL EXPOSURE

Lithographic film developer, containing <1 w/w% of the notified chemical FPC-156, is transported to Australia in 20 foot shipping bulk containers containing plastic cartons on wooden pallets. Each pallet (containing 51 cartons of material) is removed from the container by stacker trucks at the shipping company's warehouse, and loaded onto truck transport (involving approximately 3 workers) for delivery to the Collie Cooke store. This is a mechanical method which does not involve direct worker handling of the product. The trucks used are either closed or have side railings. The pallets are shrink wrapped and are reinforced with a support framework.

Units of film developer (in 10 litre lots) are transported
from Collie Cooke by covered transport to each client (approximately 260). The potential for worker exposure during transport and at the Collie Cooke store is very low and will occur in the event of worker mishandling or a traffic accident. Approximately 2 workers will be involved in storage and another 2 workers in dispatch.

At each client's premises the film developer is diluted with water (1 part developer with 2 parts water) and added to the developer tank. This involves 1 graphic arts tradesperson or general worker at each site. The average film processor operates with 16.3 litres of working developer in the developer tank and 40 litres in the replenishing tank.

At each site, exposure to the solution will occur during the following operations:

- removing trapped film from the developer tank (one worker approximately 2 mm/day);
- removing exhausted developer from developer tank, replacing with fresh working developer, and transfering exhausted working developer to holding tanks for neutralisation and further dilution before disposal (one worker approximately 45 min/2 months);
- mixing developer for the replenisher tank (one worker approximately 5 mm as required); and
- engineering service of reprographic (film processing) equipment containing diluted solution.

The notifier states that during film processing, workers will not come into contact with the solution, however, fumes may be released to the atmosphere.

The worker environment will vary for each user. Most film processors will be housed in airconditioned sites. Workers will be encouraged to use protective gloves and safety glasses when handling the material.

7. PUBLIC EXPOSURE

Lithographic film developer, (containing <1% w/w of the notified chemical FPC-156) will be imported to Australia in shipping bulk containers containing plastic containers on wooden pallets. These pallets (containing 51 ten litre containers of material) will be removed mechanically from the ship and loaded onto trucks for transportation to Collie Cooke. Covered transport will be used to transport units of film developer (in 10 litre lots) from Collie Cooke to each client. There is low potential for public exposure to the notified chemical during shipment and distribution.

At the client's premises, the film developing product is diluted with water (1 part product with 2 parts water), added to developing tanks and used in reprographic eqipment to fix photographic products. The exhausted, diluted product is
removed from the equipment into a holding tank where it is further diluted with water before entry into the sewerage system or, when disposal by that method is not permitted, into holding tanks for removal to a waste treatment plant.

The public should not be directly exposed to the chemical as the film developer will only be used by professionals in lithographic processing laboratories.

8 ENVIRONMENTAL EXPOSURE

Release

The lithographic product containing the notified substance is diluted with water and added to the developing tank of an automatic film processor. The developing tank is continually replenished with more solution. Roughly every two months, the developing tank is emptied and refilled with fresh developer.

Clients using the new photographic chemical are likely to have variable work practices. However, in general it is expected that spent solutions will be directed to a balancing tank with a minimum size of 200 L and detention time of at least an hour. Samples will be analysed for pH, silver, chemical oxygen demand, ammonia, thiosulphate, sulphite and sulphate to ensure that effluent meets requirements before discharge to sewer. If requirements are mot met, photographic wastes will be transported to a liquid waste disposal depot.

It is not possible to estimate concentrations of the notified substance which may enter the balancing tank because of variations in work practices form day to day and between different processing laboratories. However, levels may be expected to be low, given that the product contains <1% w/w FPC-156 before any dilution occurs.

Fate

Following discharge to sewer, FPC-156 may be expected to remain largely in solution by virtue of its moderate water solubility. Biodegrability was investigated at concentrations of 10 and 20 ppm in the modified Sturm test. FPC-156 can not be considered to be readily biodegradable as cumulative CO_2 production over 28 days was negligible (in the order of 5%). Thus the notified substance may be expected to pass through sewage treatment works and enter receiving waters largely unchanged. However, concentrations will be low in view of the low volumes of use, and neither accumulation nor bioaccumulation are expected.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological data for this chemical are not required under the Act as the import volume of FPC-156 is <1000 kg/annum, however, studies were conducted and the data submitted for assessment.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of FPC-156

Test	Species	Outcome	Reference
Oral	Rat	LD_{50}: 637 mg/kg	1
Skin irritation	Rabbit	non-irritant	2
Eye irritation	Rabbit	non-irritant	3
Skin Sensitisation	Guinea Pig	non-sensitising	4

9.1.1 Oral Toxicity (1)

This study was conducted in accordance with OECD guideline No: 401 (5).

FPC-156 in 0.5% w/v methylcellulose in water (a total of 20 ml/kg body weight) was administered by gavage to 10 CD rats (5 male and 5 female) at the following doses: 320, 506, 800 and 2000 mg/kg. Clinical observations were made over a 14 day period. All rats were subjected to necropsy. All rats treated with 800 and 8 rats treated with 2000 mg/kg died within 2 days after dosing. Two rats treated with 2000 mg/kg were killed 5 hours after treatment for humane reasons. No deaths occured in the groups given either 320 or 506 mg/kg. Bodyweight gains of the treated animals were unaffected by treatment. Clinical signs in the low treatment groups (320 and 506 mg/kg) included underactivity, staggering gait, prone position, breathing irregularities, piloerection, pigmented staining of the snout and closed eyes. These signs were also present in the high treatment groups (800 and 2000 mg/kg) along with unconsciousness, cyanosis, spastic muscles, muscle tremor, salivation and serous discharge from the eyes. Necropsy revealed no significant macroscopic legions in the 800 kg/mg group. Altered stomach and intestinal contents and fur staining around the nose and eyes was observed in the 2000 kg/mg group.

Results of this study indicate an acute oral LD_{50} of 637 kg/mg in rats of both sexes for FPC-156.

9.1.2 Skin Irritation (2)

This study was conducted in accordance with OECD guideline No:
404 (6).

A single dose of 0.5 g FPC-156 was applied by occlusive application to the closely-clipped dorsa of 3 New Zealand white rabbits. Four hours later the dressings were removed and the skin reactions assessed after a further 1, 24, 48 and 72 hours. No dermal responses were observed at the test site at any time during the over the 72 hour observation period.

9.1.3 Eye Irritation (3)

This study was conducted in accordance with OECD guideline No:
405 (7).

A single dose of 0.1 g of FPC-156 was instilled in the conjuctival sac of the right eye of each of 3 New Zealand white rabbits. The left eye served as the control. The eyes were examined 1, 24, 48 and 72 hours after treatment. Injection of the conjuctival blood vessels and very slight discharge were observed in all rabbits during the first hour after instillation. Slight chemosis was observed in one rabbit at this time. Injection of the conjuctival blood vessels remained in only one rabbit 24 hours after instillation. This rabbit recovered by 48 hours. No corrosion was observed. No deaths occured during the study and no systemic toxicity was evident. Necropsy was not performed on these animals.

The results of this study suggest that FPC-156 is not an eye irritant in rabbits.

9. 1.4 Skin Sensitisation (4)

This study was conducted in accordance with OECD guideline No:
406 (8).

The Magnusson-Kligman Maximisation Test was used. Test animals were Dunkin-Hartley guinea-pigs.

<u>Primary skin irritation screen</u>

Four guinea-pigs were injected intradermally with 0.1 ml of FPC-156 in paraffin oil and 0.1 ml of FPC-156 in Freund's Complete Adjuvant (FCA). The concentrations of FPC-156 chosen were 0.5, 1 and 3% in half the animals, and 5, 10 and 30% in the other half. Reactions were assessed 24 hours, 48 hours, and 7 days after treatment.

Three guinea-pigs were injected intradermally with 0.1 ml of FCA. Twenty-five days later, 0.03 ml

topical applications of 3, 5, 10 and 30% FPC-156 in propylene glycol were made to 4 clipped sites on the flanks of each animal, and the test sites occluded for 24 hours. Reactions were assessed 24 hours, 48 hours, and 7 days after removal of the dressings.

Based on the results of the above studies, an induction and challenge dose of 30% FPC-156 in paraffin oil and propylene glycol, respectively, were chosen for the main study.

Induction

Twenty test animals (10 male and 10 female) were injected intradermally (either side of the dorsal median line) with 0.1 ml FCA, 30% w/v FPC-156 in paraffin oil and 30% w/v FPC-156 in FCA. Control animals (also 10 male and 10 female) were treated identically to the test animals except that test material was replaced by vehicle during the induction stage. On day seven, all animals were induced with the application of 10% sodium lauryl sulphate in petrolatum to the clipped dorsa of each animal. On day 8, topical applications of 0.6 ml 30% w/v FPC-156 in paraffin oil were made. The test sites were occluded for 48 hours and then wiped clean.

An intradermal injection of 30% w/v FPC-156 in paraffin oil or FCA caused slight or moderate erythema in most test animals. Topical applications of 30% w/v FPC-156 in paraffin oil caused barely detectable or slight erythema and occasional eschar and exfoliation.

Challenge

On day 21, both flanks of each animal were clipped. The following day, one flank received a topical application of 0.03 ml propylene glycol and the other 30% FPC-156 in propylene glycol. The test site was occluded for 24 hours and then wiped clean. The challenge sites were assessed for sensitisation reactions 24 and 48 hours after the removal of dressings. Challenge application of 30% FPC-156 in propylene glycol caused slight erythema in one test animal and no controls.

The results of this study suggest that FPC-156 is not a skin sensitiser in guinea-pigs.

9.2 Genotoxicity: Salmonella typhimurium Reverse Mutation Assay (9)

This study was conducted in accordance with OECD guideline No:
471 (10).

FPC-156 at concentrations of 0, 50, 158, 500, 1580, and 5000 4/plate was tested for gene mutation according to the direct plate incorporation method using *Salmonella typhymurium* strains TA 98, TA 100, TA 1535 and TA 1537, both in the presence and absence of microsomal activation. Positive controls used were sodium azide, 2-aminoanthracene, 9- aminoacridine, 2-nitrofluorene and benzo[a]pyrene. No dose- dependant increase in the number of revertant colonies was observed in

any of the strains exposed to FPC-156, both in the presence and absence of microsomal activation. Marked increases in the number of revertant colonies were induced by positive controls.

The results of this study suggest that FPC-156 is not mutagenic under the experimental conditions reported

9.3 Overall Assessment of Toxicological Data

In animal studies, FPC-156 had low acute oral toxicity (LD_{59}-637 mg/kg). It was neither an eye or skin irritant in rabbit nor a skin sensitiser in guinea-pig.

FPC-156 was negative in the *Salmonella typhymurium* histidine reversion test.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Environmental effects testing is not a requirement for low volume chemicals under the Act. However, the notifier has provided acute toxicity results from static tests on *Daphnia magna* and rainbow trout. The results indicate slight toxicity to daphnids (48 h EC_{50} = 24 mg/L) and negligible toxicity to fish (96 h LC_{50} = 141 mg/L).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Given the low volumes of use for this new photographic chemical, and its low concentration in lithographic developing solutions, concentrations in effluents entering receiving waters are expected to remain well below 1 ppm, thus conferring a safety margin of several orders of magnitude for aquatic fauna. The predicted environmental hazard is minimal.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

FPC-156 will be imported in small volumes (< 1000 kg/annum) and constitutes less than 1% of the imported film processing product. It contains no hazardous impurities. Animal toxicity data suggest that it is not an irritant or skin sensitiser and has low acute toxicity. The chemical is stable at ambient temperatures, is non-flammable, has no known explosive properties, but may react with oxidisers.

Due to the low potential for public exposure and the low concentration of FPC-156 used for lithographic processing, there should be negligible risk to public safety.

Based on the above information, the notified chemical is not expected to pose a significant hazard to

workers when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to FPC-156 the following guidelines and precautions should be observed:

- Engineering control procedures such as good general ventilation should be used in areas where the chemical
- will be handled or used in reprographic equipment.

- Suitable personal protective equipment which complies with Australian Standards should be worn when handling the developer solution, such as chemical-type goggles with face shield recommended to prevent eye contact (11), chemically resistant gloves (12) and protective clothing (13) to prevent skin contact.

- Good work practices should be implemented to avoid splashing or spillages.

- Good personal hygiene practices, such as washing of hands prior to eating food, should be observed.

- A copy of the MSDS for products containing the notified chemical, such as Lithographic film developer LD-835, should be easily accessible to employees working with working with these products.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for LD-835 (Attachment 1) was provided in Worksafe Australia format (14). This MSDS was provided by Collie Cooke Limited 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 Collie Cooke Limited.

15. REOUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of FPC-156 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. LSR Report 92/0288 *M-3204: Acute oral toxicity study in the rat,* Life Science Research Limited, 1992.

2. LSR Report 92/0152 *M-3204: Acute derinal irritation/corrosion test in the rabbit,* Life Science Research Limited, 1992.

3. LSR Report 92/0170 *M-3204: Acute eye irritation test in the rabbit,* Life Science Research Limited, 1992.

4. LSR Report 92/0271 *M-3204: Delayed contact hypersensitivity study in guinea-pigs,* Life Science Research Limited, 1992.

5. OECD Guidelines for Testing of Chemicals - *Acute Oral Toxicity* No: 401, 1987.
6. OECD Guidelines for Testing of Chemicals - *Acute Dermal Irritaton/Corrosion* No: 404, 1981.

7. OECD Guidelines for Testing of Chemicals - *Acute Eye Irritaton/Corrosion* No: 405, 1987.

8. OECD Guidelines for Testing of Chemicals - *Skin Sensitisation* No: 406, 1981.

9. LSR Report 92/0371 *M-3204: Assessment of mutagenic potential in histidine autotrophs of* Salmonella typhimurium, Life Science Research Limited, 1992.

10. OECD Guidelines for Testing of Chemicals - *Genetic Toxicology:* Salmonella typhymurium, *Reverse Mutation Assay* No: 471, 1982.

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

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

13. Australian Standard 3765.1-1990 *Clothing for Protection against Hazardous Chemicals Part 1 Protection against General or Specific Chemicals* Standards Association of Australia Publ, Sydney, 1990.

14. National Occupational Health and Safety Commission, *Guidance Note for Completion of a Material Safety Data Sheet,* 3rd Edition, Australian Government Publishing Service Publ., Canberra, 1991.