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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

FPC-156

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

FPC-156

1. APPLICANT

Hanimex Pty Ltd, 108 Old Pittwater Rd, Brookvale NSW, 2100.

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 20°C and 101.3 kPa:	white powder
Odour:	
Melting Point/Boiling Point:	not determinable, decomposes at 295 °C prior to melting
Glass-transition Temperature:	°C
Relative Density:	1400 kg/m^3 {for density}
Vapour Pressure:	3.1 x 10^{-14} kPa at 25°C
Surface Tension:	72.0 mN/m at 0.18 g/L (saturated)
Water Solubility:	0.17 g/L @ 20°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: $k(h^{-1})$ = 0.00210 @ pH 9 and 25°C; environmental half-life: $te_{1/2}$ = 329 hours {state pH range and temp.}
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°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 quantities below 1000 kg per annum. 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(of the notified chemical alone): >99.9%

Toxic or hazardous impurity/impurities: none

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

5. INDUSTRIAL USE

FPC-156 will be imported into Australia as a component of X-ray film developer. The developer will contain <1 w/w% of the notified chemical. Less than 1000 kg of the notified chemical will be imported per annum.

6. OCCUPATIONAL EXPOSURE

The laser imager film developer,(containing <1 w/w% of the notified chemical FPC-156) is transported to Australia in shipping bulk containers containing plastic containers (or cartons) on wooden pallets. Each pallet 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 Hanimex 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 developer (in 10 litre cartons) are transported from Hanimex by covered transport to each client (approximately 11). The potential for worker exposure during transport and at the Hanimex store is very low and will only 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 1 part water) and added to the developing tanks of X-ray processing equipment. This involves 1 radiographer or general worker at each site. The average X-ray processor operates with approximately 8 litres of working developer in the developer tank and 20 litres in the replenishing tank.

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

- manually removing X-ray film from the developer tank (one worker approximately 2 min/day);
- removing exhausted developer from developer tank, replacing with fresh developer, and transfering exhausted 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 min as required); and
- engineering service of the 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 work environment will vary for each user. Most X-ray 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

The public is unlikely to be exposed to the chemical during importation, distribution and use. The chemical is distributed in 10 litre cartons directly to clients, for use in dilute form in the developing tanks of X-ray processing equipment. The exhausted developing fluid is removed to a waste treatment plant after use.

8. ENVIRONMENTAL EXPOSURE

. Release

The photographic 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. Approximately 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 from day to day and between different processing laboratories. However, levels may be expected to be low, given that the product contains only ppm 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

Toxicological data for this chemical are not required under the Industrial Chemicals (Notification and Assessment) Act 1989 (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	Rabbit	non-irritant	2
Eye	Rabbit	non-irritant	3
Skin	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 surviving 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 staining of fur 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.

Results of this study indicate that FPC-156 is not a skin irritant in rabbits.

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. Instillation of the test material produced a very slight initial pain response. 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.

Primary skin irritation screen

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 µl/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-dependent 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_{50} = 637 mg/kg). It was neither an eye nor 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 photographic 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 oral toxicity. The chemical is stable at ambient temperatures, is non-flammable, has no known explosive properties, but may react with oxidisers.

The public is unlikely to be exposed to the chemical during importation, distribution and use.

Based on the above information, the notified chemical is not expected to pose a significant hazard to occupational or public health 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 film processing 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 the X-ray film developer RD·F-20, should be easily accessible to employees working with these products.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for RD·F-20 (Attachment 1), containing the notified chemical FPC-156, was provided in Worksafe Australia format (14). This MSDS was provided by Hanimex 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 Hanimex Pty Ltd.

15. REQUIREMENTS 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 dermal 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.