File No: NA/264

Date: 14 June 1995

# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

#### **FULL PUBLIC REPORT**

**FPC-160** 

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Director Chemicals Notification and Assessment

#### **FULL PUBLIC REPORT**

#### **FPC-160**

### 1. APPLICANT

Hanimex Pty. Ltd. of 108 Old Pittwater Rd., Brookvale, NSW, 2100 has submitted a standard notification for FPC-160.

# 2. <u>IDENTITY OF THE CHEMICAL</u>

Chemical name: 3-Sulfinobenzoic acid

**Chemical Abstracts Service** 

(CAS) Registry No.:

Not yet allocated.

Other name(s): CS-7299

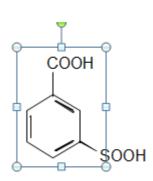
M-3216

**Trade name:** FPC-160, which is a component of a photographic

product CP-47L P2-R Part A

**Molecular formula:**  $C_7H_6O_4S$ 

Structural formula:



Molecular weight: 186

#### Method of detection and determination:

UV/Vis spectrum, IR spectrum, NMR and mass spectra

Spectral data:

UV/Vis spectrum:  $\lambda$  max was observed at approximately 275 nm (shoulders) in

distilled water, acidic and alkaline solutions

IR spectrum: an IR spectrum was submitted which was characterised by a

few, strong distinct peaks (813, 1034, 1691 cm<sup>-1</sup>); strong sharp bands of medium-strong intensity (1180-1380 cm<sup>-1</sup>), sharp bands of variable intensity below 1100 cm<sup>-1</sup>; medium, sharp doublets (1411 and 1422 cm<sup>-1</sup>, 1576 and 1598 cm<sup>-1</sup>) and a very strong, broad band between 2100 and 3400 cm<sup>-1</sup>.

NMR spectrum was submitted and was consistent with the structure of the notified chemical, as were the other spectra.

#### 3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: cream powder in pure form

**Melting Point:** 188°C (during heating the test

> substance decomposed; OECD guideline 102)

1400 kg/m<sup>3</sup> **Density:** 

1.0 x 10<sup>-6</sup> Pa at 25°C Vapour Pressure:

Water Solubility: 42.3 g/L at 20°C at pH 9.6

Fat Solubility: 32.8 mg/100 g water at 37°C

**Partition Co-efficient** 

(n-octanol/water) log Pow: -2.82 at 20°C

Hydrolysis as a function of pH:  $t_{1/2}$  > one year at pH 4,7 and 9; T = 50°C

 $K_{oc}$  of soil 1 = 136 Adsorption/Desorption:

> (sandy loam),  $K_{oc}$  of soil 2 = 90.8

(clay loam),

 $\dot{K}_{oc}$  of soil 3 = 153(sandy silt loam)

**Dissociation Constant** 

pKa:  $3.53 \pm 0.08$ 

**Flash Point:** Not applicable to solids

**Autoignition Temperature:** 391°C

**Explosive Properties:** Not susceptible to thermal, friction or

mechanical shocks

**Oxidising Properties:** Stable

**Surface Tension:** 72.4 mN/m at 21°C, 1000 mg/L

Particle size distribution: < 10 µm 0.01%

> 10-30 µm 0.02% 0.54% 30-75 µm 75-125 µm 3.40% 125-400 µm 48.28% >400 µm 46.65%

#### **Comments on physico-chemical properties:**

The hydrolysis of the notified chemical as a function of pH was studied according to EEC Method C.10. The results showed that the hydrolysis rates at pH 4, 7 and 9 and 50°C were such that less than 10% hydrolysis was observed at 5 days. The results indicate that the notified chemical is hydrolytically stable under acid, neutral and alkaline conditions.

The soil adsorption/desorption properties were studied according to OECD TG 106. The soils used in the study were a clay loam (%OC 1.7, pH 5.7), sandy loam (%OC 1.0, pH 6.1) and sandy silt loam (%OC 0.8, pH 4.5). Adsorption was determined by mixing the soil with 0.01 M CaCl2 for 18 hours at 20°C at a rate that maintained the soil in suspension. The suspensions were separated by centrifugation and the supernatant removed and the concentration of the notified chemical determined. Less than 25% adsorption had occurred in all three soils. As a result desorption studies were not required. The Kd (adsorption coefficient) and Koc (adsorption coefficient as a function of the organic carbon content) values calculated from adsorption results were:

| Soil            | Kd  | Koc  |
|-----------------|-----|------|
|                 |     |      |
| Sandy loam      | 1.4 | 136  |
| Clay loam       | 1.5 | 90.8 |
| Sandy silt loam | 1.2 | 153  |

The Kd and Koc values indicate that the notified chemical would be mobile in the soils tested.

## 4. PURITY OF THE CHEMICAL

**Degree of purity:** typical concentration 97%

lower/upper limits 94%/100%

Toxic or hazardous impurity/impurities: none

Chemical name

Weight percentage
(typical/lower/upper)

3-sulfobenzoic acid 2%/0%/5%

water 1%/0%/2%

Additives/Adjuvants: none

#### 5. INDUSTRIAL USE

FPC-160 in pure form is a cream powder and is intended to be used as a stabilising agent for photographic paper in photofinishing. FPC-160 will be brought in as a component of a photographic chemical formulation, CP-47L P2-R Part A.

It is estimated that FPC-160 will be imported at a volume of 0.1-1 tonnes per year from 1995 - 1997, rising to 1-10 tonnes per year from 1998 - 1999.

#### 6. OCCUPATIONAL EXPOSURE

The formulated product will be imported as a dilute aqueous solution in 2.5 litre plastic sealed bottles with screw type plastic tops. The bottles are packed into 4 bottle cartons, with the cartons palletised. The chemical will be shipped by sea in standard shipping containers. These are transported to Hanimex's Sydney warehouses by road transport. The cartons will be despatched to customers by road (and sea to non-mainland locations).

The chemical is expected to initially go to only a small number of waterless photolabs. After alterations to photolab equipment to modify pumps and/or controllers to reduce their capacity, the number is expected to increase to several hundred photolabs and several other labs at the end of a three year period. With, on average, three staff in each lab, potentially close to 2000 workers may be exposed to the notified chemical, though only one person at each site will be handling the notified chemical.

The number of workers potentially exposed per photolab will be one worker charging the developing machine by pouring in the contents of the plastic containers, which will take 0.2 hours/day for 125 days/year on average, and 2 to 5 workers involved in machine operation, which will take 8 hours/day for 250 days/year on average. These processes take place mainly in closed systems and where possible local exhaust ventilation is installed.

#### 7. PUBLIC EXPOSURE

CP-47L PR-2 Part A will be imported to Australia by ship in 2.5 L plastic sealed bottles and distributed by road to Hanimex's Sydney warehouses and then to potential customers. Public exposure to the notified chemical during its storage or distribution is not expected to occur.

Only commercial use of CP-47L PR-2 Part A will occur. It will be used in fully automated photo minilabs which are mostly closed systems. No public exposure to the notified chemical is expected to occur during this use. Although CP-47L PR-2 Part A will be used undiluted in mini photolabs, residue levels of FPC-160 on end-use products are expected to be extremely low and no significant public exposure is expected to occur.

Disposal of any waste notified chemical will be to landfill or sewerage. The concentration of FPC-160 in waste solutions entering the sewerage has been estimated by the notifier to be < 0.0002 %. Further dilution will occur on entering the sewerage and this will result in extremely low concentrations of the notified chemical. Disposal of the notified chemical is not expected to result in significant public exposure.

#### 8. ENVIRONMENTAL EXPOSURE

#### Manufacture/Import Volume

No manufacturing of the notified chemical takes place in Australia. The import volume of the notified chemical will be:

1995: 100 - 1000 kg 1996: 100 - 1000 kg 1997: 100 - 1000 kg 1998: 1000 - 10,000 kg 1999: 1000 - 10,000 kg

The chemical will be imported in a 3% aqueous solution in 2.5 L plastic bottles in cartons of 4 bottles. The cartons are palletised and wrapped in a plastic film.

#### Use

The notified chemical is a component of a photographic processing material that is distributed to photographic processing laboratories. The notified chemical will be used as a stabilising agent in the photofinishing process. It will be charged into a developing machine for the automatic photofinishing operation.

There are approximately 2000 photo labs in Australia of which 600 are supplied by Hanimex. They are located in retail centres all around the country. The notifier estimates that only about 20 labs will be using the notified chemical by the end of 1995 with another 200 labs changing over by the end of 1996 and 600 by the end of 1997. The change over requires equipment modification which will take up to 2 years. FPC-160 will be used in the same process as FPC-159 (previously notified chemical - NA/258).

# Release

The notifier has provided an estimate that spillage from typical use at a photolab might be 1 spill in every 100 loads. The volume spilt would be about 25 mL from 2.5 L, or about 1%, of which only 3% would be the notified chemical. The amount of chemical lost to the environment is minimal, with the spill collected by mopping. Used containers are typically rinsed with water and added to the solution to be used in the photolab. Used containers could then be recycled (plastic feedstock) or disposed to landfill.

All labs have two processing machines; one for film processing and one for paper processing. Paper processing machines generally have 3 chemical tanks that are replenished from holding tanks according to the amount of emulsion throughput. The resultant overflow is collected for disposal along with the waste from other machines within the lab.

The 3% aqueous solution is used without dilution in the paper developer tank. The developer overflow accounts for approximately 20% of the total paper process waste. This liquid waste is disposed of to sewer according to Photographic Uniform Regulations for the Environment (PURE). Balancing pits or tanks are used to combine photographic wastes to achieve neutralisation (ie balancing of acidic vs neutral waste) and dilution. Therefore, the notified chemical will be further diluted by other aqueous photographic

solutions used in the processing, to give an estimated concentration of 0.6%, with further dilution at the balancing pit from sink waste to give a concentration at the photolab of less than 0.0002% (2 ppm). No other chemical treatment prior to disposal is needed for the notified chemical.

#### Fate

When disposed to sewer the notified chemical is likely to remain in solution because of its high water solubility and low partition coefficient. The notified chemical is not expected to persist in the environment as it is readily biodegradable.

The biodegradation of the notified chemical was investigated according to the Modified Sturm Test (OECD TG 301B). The notified chemical was added to vessels containing inoculated (with activated sludge) mineral salts medium, to give a nominal test concentration of 10 mg.L-1, and incubated for 42 days. The theoretical CO<sub>2</sub> (TCO<sub>2</sub>) production of the notified chemical is 106.4 mgCO<sub>2</sub>. Cumulative CO<sub>2</sub> production by the notified chemical was equivalent to 13% of the TCO<sub>2</sub> after 15 days of incubation, 68% of the TCO<sub>2</sub> after 25 days and 80% of the TCO<sub>2</sub> at the end of the study. Substances are considered to be readily biodegradable if CO<sub>2</sub> production is equal to or greater than 60% of the theoretical value within 10 days of the level first achieving 10%. Therefore, the notified chemical can be considered to be readily biodegradable.

The notified chemical is unlikely to bioaccumulate or accumulate in sediment due to its low partition coefficient (Log  $P_{OW} = -2.82$ ) and its high water solubility (42.3 g.L<sup>-1</sup>).

# 9. EVALUATION OF TOXICOLOGICAL DATA

# 9.1 Acute Toxicity

Table 1. Summary of the acute toxicity of FPC-160

| Test               | Species    | Outcome                       | Reference |
|--------------------|------------|-------------------------------|-----------|
| Acute Oral         | Rat        | LD <sub>50</sub> > 2000 mg/kg | (1)       |
| Acute Dermal       | Rat        | LD <sub>50</sub> > 2000 mg/kg | (2)       |
| Skin sensitisation | Guinea-pig | Moderate sensitiser           | (3)       |

Results of irritation studies for the aqueous solution to be used in Australia were assumed on the basis of pH.

| Skin irritation | Rabbit | Corrosive           | (-) |
|-----------------|--------|---------------------|-----|
| Eye irritation  | Rabbit | Severely irritating | (-) |

#### 9.1.1 Oral Toxicity (1)

This study was performed according to OECD Guideline No. 401 (4).

FPC-160 was administered to CD rats (5/sex) at a single oral dose of 2000 mg/kg in aqueous 0.5% methylcellulose. Animals were observed for 14 days and then sacrificed and subjected to gross necropsy.

Two females died during the first overnight period. Treatment-related clinical signs observed were underactivity, staggering gait, piloerection, hunched posture and closed eyes. Clinical signs were similar in the other animals apart from closed eyes.

Body weight gain was unaffected by treatment in surviving animals.

Macroscopic examinations found no evidence of treatment-related effects in either animals which died during the study or which survived the study.

In conclusion, the oral LD<sub>50</sub> of FPC-160 was > 2000 mg/kg.

#### 9.1.2 Dermal Toxicity (2)

This study was performed according to OECD Guideline No. 402 (5).

FPC-160 on a gauze patch was applied to the shaved back of CD rats (5/sex) at a single dose of 2000 mg/kg to an area approximately 25 cm<sup>2</sup> for both sexes which was covered by an occlusive dressing for 24 hours. Animals were observed for 14 days and then sacrificed and subjected to gross necropsy.

No mortalities occurred during the study. No clinical signs were observed apart from slight erythema up to the first 4 days post-dosage. Skin was discoloured yellow by the notified substance. No other clinical signs were noted.

Body weight gains were unaffected by treatment. Macroscopic examinations found no evidence of treatment-related effects.

In conclusion, the dermal  $LD_{50}$  of FPC-160 is > 2000 mg/kg.

#### 9.1.3 Skin Irritation

This study was not performed. Based on the low pH (= 1.84) of an aqueous solution of the notified chemical which would be used in practice, the solution is assumed to be corrosive.

### 9.1.4 Eye Irritation

This study was not performed. The compound will be used in an aqueous solution with pH of approximately (= 1.84). The notified chemical in this solution is therefore assumed to be severely irritating/corrosive to the eye. Based on the low pH (= 1.84), the notified chemical is classified as severely irritating.

#### 9.1.5 Skin Sensitisation (3)

This study was performed in accordance with OECD Guideline No. 406 (6). The test used was the Magnusson and Kligman test (7) in the Dunkin-Hartley guinea-pig.

No positive control was used, but historic positive control data was provided using 2-mercaptobenzothiazole, showing that the strain of guinea-pig used in the study was capable of developing a delayed contact hypersensitivity response.

#### Induction

On day 1, guinea-pigs (10/sex) were intradermally injected with three pairs of injections in the clipped dorsal skin of the scapular region as follows:

- A) FPC-160, 10% w/v, in distilled water;
- B) FCA, and
- C) 10% w/v FPC-160 in FCA

On day 7, animals were injected in the clipped dorsal area with 10% w/v sodium lauryl sulphate in petroleum to enhance dermal absorption of formulations administered the next day.

On day 8, the scapular region between the injection sites was treated with 0.6 mL of 50% (w/w) FPC-160 in water, applied by an absorbent patch and secured with by an occlusive tape for 48 hours. Skin reactions were assessed immediately after removal of dressing.

Negative controls (5/sex) were treated identically to test animals with the omission of notified chemical.

Intradermal injection of 10% w/v FPC-160 in water caused ulceration (7 males, 3 females). Occluded topical administration of 50% w/v FPC-160 in purified water caused exfoliation (10 males, 8 females) and less frequently eschar.

#### Challenge

Test and control animals were challenged two weeks after the epidermal application i.e on day 22 by occluded application as follows: application of purified water to the left flank and 50% w/v and 10% w/v FPC-160 in purified water to two sites on the right flank for 24 hours. Skin sensitisation was assessed 24 and 48 hours after removal of dressing. All animals were killed at the end of the study.

Thirteen and twelve animals treated with test substance showed a skin reaction (erythema) in response to the 50% and 10% test substance concentrations, respectively. Four animals showed scaliness at 1%. No skin reaction was noted at 0.2%. No reaction was observed in control animals.

Overall the sensitisation rate was 65% at 50% concentration.

#### Other Results

No mortalities and no clinical signs of toxicity were observed in the study. Body weight gains of all animals were in the anticipated range.

It is concluded that FPC-160 is a strong skin sensitiser in guinea-pigs.

# 9.2 Repeated Dose Toxicity (8)

This study was performed according to OECD Guideline No. 407 (9).

Based on a preliminary dose range finding study, CD rats (5/sex/group) were given FPC-160 orally by gavage at doses of 0, 30, 150 or 1000 mg/kg/day for 28 days. The vehicle was 0.5% methylcellulose. Animals were sacrificed 24 h after the last dose. Gross and microscopic examinations were conducted.

One high dose female died on day 29 of the study, during blood sampling. At 1000 mg/kg/day, salivation was observed in both sexes throughout the dosing period. Body weight gains of treated animals were comparable to that of control animals.

Haematology and clinical chemistry values were unaffected by treatment.

Liver weights of high dose females were elevated in comparison to control animals.

Macroscopic and microscopic examinations revealed no treatment-related effects.

In conclusion, FPC-160 produced effects in rats via the oral route at the highest dose tested i.e. 1000 mg/kg/day.

#### 9.3 Genotoxicity

### 9.3.1 Salmonella typhimurium Reverse Mutation Assay (10)

This study was performed according to OECD Guideline No. 471 (11).

Strains used were *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100 and *Escherichia coli* strains WP2 and WP2 *uvrA*. The assays were performed in two independent experiments both without and with metabolic activation (using S9 mixture). Each concentration including controls was tested in triplicate. The following concentrations of FPC-160 were tested: 5, 50, 500, and 5000  $\mu$ g/plate. The test substance was dissolved in filtered water. Positive reference controls used were a) sodium azide, 9-nitrofluorene, 9-aminoacridine and 2-aminoanthracene in the absence of metabolic activation and b) 2-aminoanthracene and benzo( $\alpha$ )pyrene in the presence of metabolic activation.

Up to the highest investigated concentration no toxic effects were observed on background growth of any strains either in the absence or presence of metabolic activation.

No increase in revertant colony numbers was observed for any of the strains at any dose level of FPC-160 used, in the absence or presence of metabolic activation.

The positive controls produced increases in revertant numbers indicating that the test conditions were optimal.

In conclusion, under the conditions of these assays, FPC-160 did not induce point mutations by base pair changes or frameshifts in any of the four *Salmonella typhimurium* strains used.

# 9.3.2 *In Vitro* Clastogenic Activity of FPC-160 in Cultured Human Lymphocytes (12)

This study was performed according to OECD Guideline No. 473 (13).

FPC-160 was dissolved in culture medium. The notified chemical was tested in the absence and presence of metabolic activation (S9 mix) in duplicate in two independent experiments. Concentrations chosen were based on a preliminary test to investigate the toxicity of FPC-160.

Lymphocyte cultures were cultured for 48 h and in the absence of S9 mix were exposed continuously for 19 or 43 hours, while with S9 mix exposure was limited to 3 hours and cells were harvested 16 or 40 hours later.

Concentrations tested were as follows:

#### First cytogenetic test:

\* with and without S9 mix:19 hour sampling time - 250, 500 1000, 2000, 3000 and 4000 μg/mL 43 hour sampling time - 500, 1000, 1500, 2000 and 3000 μg/mL

### Second cytogenetic test:

- \* without S9 mix: 19 hour sampling time 500, 1000, 2000, and 2500  $\mu$ g/mL 43 hour sampling time 1500 and 2000  $\mu$ g/mL
- \* with S9 mix: 19 hour sampling time 1000, 2000, 3000, 3300, 3600 and 3900 μg/mL

The positive controls used were chlorambucil without S9 mix and cyclophosphamide with S9 mix.

The mitotic index of each culture was calculated by counting the number of metaphases per 1000 cells. Metaphases containing 46 chromosomes were analysed. Chromosome aberrations were scored by examination of 100 metaphases per culture, and the frequencies of cells with one or more aberrations were calculated both including and excluding gap-type aberrations.

#### First cytogenetic test:

- without S9 mix at 19 hour sampling time a reduction in mitotic activity was observed at concentrations of 2000 (67%) and 3000 (95%)  $\mu g/mL$ , as well as cells. No metaphases were seen at 4000  $\mu g/mL$ , while at 43 hour sampling time dose-related toxicity was observed with reductions in mean mitotic activity of 26, 32, 51, 66 and 99% at FPC-160 concentrations of 500, 1000, 1500, 2000 and 3000  $\mu g/mL$ , respectively. At 2000  $\mu g/mL$  a significant increase in aberrant cell frequency (including gaps) was observed at 19 hours, while at 43 hours a significant increase in aberrant cell frequency (excluding gaps) was observed.
- with S9 mix at 19 hour sampling time a reduction in mitotic activity was observed at concentrations of 1000 (30%) and cells. No metaphases were seen at 4000  $\mu g/m L$ , while at 43 hour sampling time dose-related toxicity was observed with reductions in mean mitotic activity of 29 and 60% at FPC-160 concentrations of 1500 and 3000  $\mu g/m L$ , respectively. No increase in aberrant cell frequencies including and excluding gaps was observed.

#### Second cytogenetic test:

- without S9 mix at 19 hour sampling time a reduction in mitotic activity was observed at concentrations of 2000 (58%) and 2500 (74%)  $\mu g/mL$ , respectively, while at 43 hour sampling time dose-related toxicity was observed with reductions in mean mitotic activity of 49 and 64% at FPC-160 concentrations of 1500 and 2500  $\mu g/mL$ , respectively. At 2500  $\mu g/mL$  (19 hour sampling time) when gaps were included, a significant increase in aberrant cell frequency was observed. At 2000  $\mu g/mL$  (43 hour sampling time) when gaps were included, a significant increase in aberrant cell frequency was also observed.

- with S9 mix, no reduction in mitotic activity was observed at concentrations up to 3000  $\mu$ g/mL; at concentrations > 3000  $\mu$ g/mL cells but not metaphases were seen. No increase in aberrant cell frequencies including and excluding gaps was observed.

The positive controls produced significant increases in the frequency of aberrant cells responses indicating that the test conditions were optimal.

The increases in aberrant cell frequencies at 2000 and 2500  $\mu g/mL$  in the absence of S9 mix occurred at concentrations which were toxic. Also an increase at 2000  $\mu g/mL$ , when gaps were excluded, at 43 hour sampling time was observed only in the first test and not the second and individual aberrant cell frequencies were within the historical solvent control range excluding gaps. Therefore the increase in gap-type aberrations was considered not to be biologically significant.

In conclusion, FPC-160 is not considered clastogenic under the conditions of this assay.

#### 9.4 Overall Assessment of Toxicological Data

FPC-160 was assessed as having low acute toxicity in rats with an  $LD_{50} > 2000$  milligrams per kilogram. However, females proved to be more sensitive than males with two of the five females dying during the study. Dermal  $LD_{50}$  was shown to be > 2000 milligrams per kilograms in rats. Neither of these studies reported irritant effects on the skin or on the gastrointestinal tract. However, because of the low pH (=1.8) of an aqueous solution of the notified chemical no skin or eye irritation studies were done and it was assumed that the notified chemical in the form in which it is to be used, would be a strong irritant/corrosive to the skin and the eye. The chemical would also therefore be expected to irritate mucus membranes of the nose if exposure occurs. FPC-160 was a strong skin sensitiser in the guinea pig. A 28 day repeated dose toxicity study showed minor liver effects in females (enlarged liver). However, this was not associated with any biochemical or pathological changes. It is consistent with the increased sensitivity of females in the acute oral toxicity study. Once again, no gastric irritation was reported at necropsy in the study.

FPC-160 was negative in the Ames test and in the chromosome aberration tests performed. It therefore, is not classified as mutagenic.

#### 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicological studies have been provided.

| Test              | Species       | Result                            |
|-------------------|---------------|-----------------------------------|
| Acute toxicity    | Rainbow trout | 96h LC50 > 100 mg.L <sup>-1</sup> |
| Acute toxicity    | Daphnia magna | 48h EC50 > 100 mg.L <sup>-1</sup> |
| Reproduction      | Daphnia magna | 21d EC50 > 100 mg.L <sup>-1</sup> |
| Growth inhibition | Algae         | 96h EC50 > 100 mg.L <sup>-1</sup> |
|                   | Selenastrum   |                                   |
| 1                 | capricornutum |                                   |
| Acute toxicity    | Earthworm     | LC50 > 1000 mg.kg <sup>-1</sup>   |

The above studies were conducted according to OECD test guidelines and the results indicate the notified chemical is practically non-toxic to the species tested.

# 11. <u>ASSESSMENT OF ENVIRONMENTAL HAZARD</u>

The major environmental exposure will result from the disposal of spent processing solutions to sewer at an estimated concentration of 2 ppm. Further dilution of the chemical would be achieved on entering the waste stream of the main sewer (5-500 ML/day) resulting in an expected concentration in the sub-ppb range. Therefore, based on the chemical's low ecotoxicity and exposure, it is expected to present negligible hazard to the environment.

# 12. <u>ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS</u>

The notified chemical is a powder with a very low fraction in the respirable range. It is however, to be imported as a dilute aqueous solution with a pH of approximately 1.8. It will therefore, be a severe eye irritant or corrosive and a severe irritant to the skin. Irritation of the respiratory mucosa could be expected if exposure occurs. The compound is also a skin sensitiser.

The main exposure will occur on charging of the photolab equipment. Most of the machine processes will take place in closed systems, and the notifier has identified that where possible, local exhaust ventilation will be used. Other workers in the photo lab are expected to be exposed only in the event of accident. Exposure during transport and storage similarly is expected not to occur under normal circumstances.

Workers who are charging laboratory equipment or who may be exposed to this chemical, should wear skin, eye and respiratory protection in the form of suitable gloves, protective clothing, goggles and respiratory protection.

No significant public exposure to the notified chemical is expected to occur through the intended commercial use or via contact with treated end-use products.

#### 13. **RECOMMENDATIONS**

To minimise occupational exposure to FPC-160, the following guidelines and precautions should be observed:

. when using the notified chemical the following protective equipment should be used:

respiratory protection conforming to Australian Standards (AS) AS 1715 (14) and AS 1716 (15),

eye protection conforming to Australian standard. AS 1337-1984 (16) and 1336-1982 (17).

impervious rubber gloves conforming to AS 2161 (18), and

long-sleeved work overalls conforming to AS 3765.2 (19)

- good work practices should be implemented to avoid splashing and any possible formation of mists.
- good personal hygiene practices should be observed.
- . A copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

#### 14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for FPC-160 was provided in Worksafe Australia format (20). This MSDS was provided by Hanimex Pty 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 Hanimex Pty Limited.

### 15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals* (*Notification and Assessment*) Act 1989 (the Act), secondary notification of FPC-160 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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- 2. Johnson, I.R., 1994: M-3216: Acute percutaneous toxicity study in the rat. Report No. 94/FIT352/1181, Pharmaco-LSR Ltd, Eye, Suffolk, IP23 7PX, England.
- 3. Johnson, I.R., 1994: M-3216: Delayed contact hypersensitivity study in the guineapig. Report No. 94/FIT355/0168, Pharmaco-LSR Ltd, Eye, Suffolk, IP23 7PX, England.
- 4. OECD Guidelines for Testing of Chemicals, Section 4 Acute Oral Toxicity No. 401, 1992.
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- 7. Magnusson B, Kligman A.M., 1970, Allergic Contact Dermatitis in the Guinea-Pig: Identification of Contact Allergens, C.C. Thomas, Springfield, Illinois, USA.
- 8. Johnson, I.R., 1994: M-3216: Four-week oral toxicity study in the rat. Report No. 94/FIT356/0288, Pharmaco-LSR Ltd, Eye, Suffolk, IP23 7PX, England.
- 9. OECD Guidelines for Testing of Chemicals Repeated Dose Oral Toxicity No. 407, 1981.
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