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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

FPC-159

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

FPC-159

1. APPLICANT

Hanimex Pty. Ltd. of 108 Old Pittwater Rd., Brookvale, NSW, 2100 has submitted a standard notification for FPC-159.

2. IDENTITY OF THE CHEMICAL

Chemical name: Hexasodium 4,4'-bis[4,6-bis(2-sulfonatoethylamino)-1,3,5-triazin 2-ylamino]-2,2'-stilbenedisulfonate

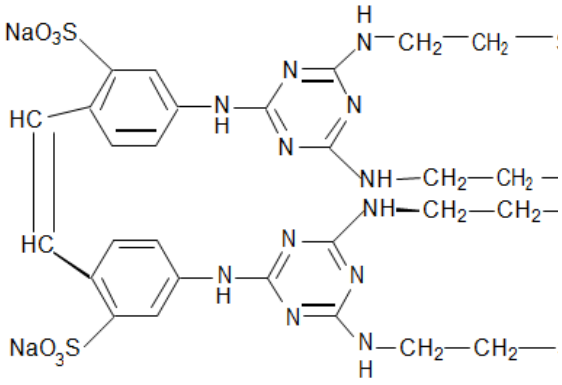
Chemical Abstracts Service (CAS) Registry No.: Not allocated

Other name(s): UVT-1738
NX-1

Trade name: FPC-159, which is a component of a photographic product called CP-47L P1-R

Molecular formula: $C_{28}H_{30}N_{12}O_{18}S_6Na_6$

Structural formula:



Molecular weight: 1153

Method of detection and determination:

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

Spectral data:

UV/Vis spectrum: two broad peaks with a maximum at 213.2 nm and another peak at 344.7 nm at pH 7; one broad peak at around 344 nm in acidic and alkaline solutions.

IR spectrum: an IR spectrum was submitted which was characterised by a few distinct peaks (between 1050 and 1600 cm^{-1}) which were broad and not completely separate from one another

NMR and mass spectra were submitted and were consistent with the structure of the notified chemical.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	yellow powder in pure form
Melting Point:	Not observed (during heating the test substance reacted or decomposed; OECD guideline 102)
Specific Density:	1780 kg/m^3
Vapour Pressure:	1.4×10^{-22} Pa at 25°C
Water Solubility:	153.6 g/L at 20°C at pH 9.6
Partition Co-efficient (n-octanol/water) log P_{OW}:	-6.6 at 20°C
Hydrolysis as a function of pH:	$t_{1/2}$ > one year at pH 4,7 and 9
Adsorption/Desorption:	$logK_{oc}$ of soil 1 = 2.06 (strong silty sand), $logK_{oc}$ of soil 2 = $\leq$ -0.22 (strong sandy loam), $logK_{oc}$ of soil 3 = 1.88 (weak sandy loam)
Dissociation Constant pKa:	5.73 $\pm$ 0.08 and 2.11 $\pm$ 0.04
Flash Point:	Not applicable to solids
Autoignition Temperature: 360°C	showed an exothermic reaction at 335°C reaching a maximum temperature of at an oven temperature of 336°C and changed to a black solid.
Explosive Properties:	Not susceptible to thermal, friction or mechanical shocks

Surface Tension:	52.6 mN/m at 20°C, 1006 mg/L
Particle size distribution:	< 2 µm 1% 2-5 µm 4% 5-10 µm 15% 10-20 µm 25% 20-50 µm 42% 50-100 µm 14%

Comments on physico-chemical properties:

The chemical is hydrolytically stable. The surface tension result indicates that the chemical should be regarded as surface active.

4. PURITY OF THE CHEMICAL

Degree of purity:	typical concentration	90%
	lower/upper limits	83%/97%

Toxic or hazardous impurity/impurities: none

Non-hazardous impurities (> 1% by weight) in the notified chemical:

Chemical name	**Weight percentage (typical/lower/upper)**
disodium 2-[4-hydroxy-6-(2-sulfonatoethylamino) -1,3,5-triazin-2-yl]aminoethylsulfonate	2%/0%/3%
trisodium 3-[4,6-bis(2-sulfonatoethylamino)-1,3,5-triazin-2-yl] aminoethylsulfonate	1%/0%/2%
sodium chloride	1%/0%/3%
sodium sulfate	1%/0%/3%
water	5%/3%/7%

Additives/Adjuvants: none

5. INDUSTRIAL USE

FPC-159 in pure form is a yellow powder and is intended to be used as a whitening agent for photographic paper in photofinishing. FPC-159 will be brought in as a component of a photographic product formulation of which it constitutes 0.5%.

It is estimated that FPC-159 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 in a 0.5% 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 20 waterless photolabs. After alterations to photolab equipment to modify pumps and/or controllers to reduce their capacity, the number is expected to increase to 560 photolabs and 40 other labs will serviced after 3 years. With on average 3-5 staff in each lab, potentially up to 3000 workers may be exposed to the notified chemical, though usually only one person at each site will be handling the notified chemical i.e. charging the developing machine.

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.

7. PUBLIC EXPOSURE

No public exposure is expected to occur during transport and storage of the notified chemical.

Since only commercial use of the photographic chemical formulation, CP-471 P1-R will occur, in fully automated photolabs which are mostly closed systems, no public exposure is expected to occur during use. Due to the low final concentration of FPC-159 used in the mini photolabs (estimated to be 100 ppm), residues of the notified chemical on end-use products will be extremely low and therefore, no significant public exposure is expected to occur.

Disposal of any waste notified chemical will be by sewage or landfill. The concentration of FPC-159 in waste solutions entering the sewerage has been estimated by the notifier to be < 4 ppm. 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

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 0.5% would be FPC-159. 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 of to landfill.

FPC-159 will be diluted with water and other aqueous solutions at 50:1 when added to the replenishing tank. This would give a concentration of 100 ppm. In a waterless photolab, dilution is achieved from water in the processing (metered from holding tank rather than direct from mains), as well as from sink washings (from cleaning racks, hands, etc). This liquid waste (including spills) is disposed of to sewer according to Photographic Uniform Regulations for the Environment (PURE) (1). Balancing pits or tanks are used to combine photographic wastes to

achieve neutralisation (ie balancing of acidic vs neutral waste) and dilution. Therefore, FPC-159 will be further diluted by other aqueous photographic solutions used in the processing, to give an estimated concentration of 10 ppm, with further dilution at the balancing pit from sink waste to give a concentration at the photolab outlet of < 4 ppm. No other chemical treatment prior to disposal is needed for FPC-159.

Fate

The ability of FPC-159 to be biodegraded was tested using the EEC C4-C test. The test result (using a nominal concentration of 15 mg TOC.L^{-1}) indicated no significant degradation of the chemical. FPC-159 was classified as not readily biodegradable. Inherent biodegradability is uncertain.

The bioaccumulation potential of FPC-159 was not investigated because of the very low partition coefficient (log P_{ow} = -6.6). Also, no bioaccumulation of the chemical is expected since it has very high water solubility, and its large molecular size is likely to inhibit membrane permeability and prevent uptake during exposure

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1. Summary of the acute toxicity of FPC-159

Test	Species	Outcome	Reference
Acute Oral	Rat	LD_{50} > 2000 mg/kg	(2)
Acute Dermal	Rat	LD_{50} > 2000 mg/kg	(3)
Skin irritation	Rabbit	Not irritating	(4)
Eye irritation	Rabbit	Mild irritant	(5)
Skin sensitisation	Guinea-pig	Moderate sensitiser	(6)

9.1.1 Oral Toxicity (2)

This study was performed according to OECD guideline No. 420 (7).

FPC-159 was administered to albino Wistar rats (5/sex) at a single oral dose of 2000 mg/kg in water. Animals were observed for 14 days and then sacrificed and subjected to gross necropsy.

No mortalities occurred during the study. No treatment-related clinical signs were observed. Body weight gain was unaffected by treatment. Macroscopic examinations found no evidence of treatment-related effects.

In conclusion, the oral LD_{50} of FPC-159 was > 2000 mg/kg.

9.1.2 Dermal Toxicity (3)

This study was performed according to OECD guideline No. 402 (8).

FPC-159 on a gauze patch was applied to the shaved back of albino Wistar rats (5/sex) at a single dose of 2000 mg/kg to an area approximately 25 cm^2 for males and 18 cm^2 for females with. Animals were observed for 14 days and then sacrificed and subjected to gross necropsy.

No mortalities occurred during the study. Lethargy was observed in two males on day 1. Skin was discoloured yellow by the notified substance. No other clinical signs were noted.

Body weight loss and no or reduced body weight gain was observed in all animals during the first week, with 3 females still showing reduced or no body weight gain in the second week. Macroscopic examinations found no evidence of treatment-related effects.

In conclusion, the dermal LD_{50} of FPC-159 was > 2000 mg/kg.

9.1.3 Skin Irritation (4)

This study was performed according to OECD guideline No. 404 (9).

FPC-159 (0.5 g), moistened with water, was applied to the intact dorsal skin, shaved 24 hours prior to chemical application, of three male NZ White albino rabbits and covered with semi-occlusive dressing for 4 hours. This was held in place by an elastic bandage. The contralateral flank was prepared similarly without the test substance. After 4 hours the test substance was removed with tissue moistened with water. The skin was observed over the next 72 hours after the removal of dressing. Skin irritation was scored according to the method of Draize (10).

No mortalities or clinical signs occurred during the study.

Skin irritation observed consisted of very slight erythema in one animal, which resolved within 24 h of removal of FPC-159. There was no evidence of an irritative effect.

It can be concluded that FPC-159 is not a skin irritant in rabbits.

9.1.4 Eye Irritation (5)

This study was performed in accordance with OECD Guideline No. 405 (11).

FPC-159 was instilled in the conjunctival sac of one eye of three male NZ White albino rabbits at a dose of 100 $\pm$ 1 mg/animal. The other eye remained untreated. Eyes were observed for 24 h after instillation. Immediately 24 h after instillation, 2% fluorescin in water (pH 7) was instilled into both eyes to quantitatively determine corneal epithelial damage. Eyes were observed for irritation up to 14 days after instillation. Eye irritation was scored according to the method of Draize (10).

No mortalities were noted in the study. No clinical signs or systemic toxicity were observed during the study.

Instillation of FPC-159 into the eye of rabbits produced mild irritation of the conjunctivae, which had resolved by the end of the observation phase. The irritation consisted of redness, chemosis and discharge. No corneal epithelial damage was found. No corrosive effects were observed.

It can be concluded that FPC-159 is a slight eye irritant in rabbits.

9.1.5 Skin Sensitisation (6)

This study was performed in accordance with OECD Guideline No. 406 (12). The test used was the Magnusson and Kligman test (13) in the Himalayan albino guinea-pig.

Formaldehyde was used as a positive control.

Induction

On day 1, 20 female guinea-pigs were intradermally injected with three pairs of injections in the clipped dorsal skin of the scapular region as follows: A) FPC-159, 5% w/v, in distilled water; B) a 1:1 mixture of FCA and distilled water, and C) 10% w/v FPC-159 in a 1:1 (v/v) mixture of FCA and distilled water. On day 8, the scapular region between the injection sites was treated, with 0.5 mL of 25% (w/w) FPC-159 using a Scotchpak non-woven patch mounted on Micropore tape and secured with Coban elastic tape for 48 hours. Skin reactions were assessed immediately after removal of dressing.

Negative controls were treated identically to test animals with the omission of test substance.

Seven test animals showed slight erythema after removal of the patch, while no negative control animals were affected.

Challenge

Test and control animals were challenged two weeks after the epidermal application ie. on day 22 with 0.05 mL of each of the following test substance concentrations 1%, 0.5%, and 0.2%, w/w in distilled water and with the vehicle on the clipped and shaved flank, using Square chambers attached to Micropore tape and secured with Coban elastic bandage 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.

Nine and three animals treated with test substance showed a skin reaction (erythema) in response to the 1% and 0.5% test substance concentrations, respectively. Four animals showed scaliness at 1%. No skin reaction was noted at 0.2%. One and two negative control animals showed erythema in response to the 1% and 0.5% test substance concentrations, respectively. Scaliness was observed in one control at the 0.2% concentration. Overall the sensitisation rate was 45% at 1% concentration (35% after taking into consideration of the control background).

The positive control produced a 70% sensitisation rate at a concentration of 0.2%.

Other Results

No mortalities and no clinical signs of toxicity were observed in the study. Body weight gain of controls was reduced in comparison to that of chemical treated animals. This could not be explained.

It is concluded that FPC-159 is a moderate skin sensitiser in guinea-pigs.

9.2 Repeated Dose Toxicity (14)

This study was performed according to OECD Guideline No. 407 (15).

Based on a preliminary dose range finding study, Wistar rats (5/sex/group) were given FPC-159 orally by gavage at doses of 0, 50, 200 or 1000 mg/kg/day for 28 days. The vehicle was water. Animals were sacrificed 24 h after the last dose. Gross and microscopic examinations were conducted.

No mortalities were recorded during the study. No clinical signs related to treatment were observed. Body weight gains of treated animals were comparable to that of control animals.

Ophthalmoscopic examinations were normal. Haematology and clinical chemistry values were unaffected by treatment.

Macroscopic and microscopic examinations revealed no treatment-related effects.

In conclusion, FPC-159 produced no toxicity in rats via the oral route up to the highest dose tested i.e. 1000 mg/kg/day.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (16)

This study was performed according to OECD Guideline No. 471 (17).

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 were tested: 100, 333.3, 1000, 3330 and 5000 μg/plate. The test substance was dissolved in filtered water. Positive reference controls used were a) sodium azide, 9-aminoacridine, daunomycine and methyl methane sulfonate in the absence of metabolic activation and b) 2-aminoanthracene 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-159 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-159 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 Mammalian Cytogenetic Test - Cultured Human Lymphocytes (18)

This study was performed according to OECD Guideline No. 473 (19).

FPC-159 was dissolved in spectroscopic quality dimethylsulphoxide. The notified chemical was tested in the absence and presence of metabolic activation (S9 mix) in duplicate in two independent experiments.

Lymphocyte cultures (obtained from a healthy male donor) were cultured for 48 h and exposed to notified chemical at the following concentrations:

* without S9 mix: 1000, 3330, 5000 μg/mL with 24 h fixation period
  5000 μg/mL with 48 h fixation period
* with S9 mix: 1000, 3330, 5000 μg/mL with 24 h fixation period
  5000 μg/mL with 48 h fixation period

In the repeat experiment, only 24 h fixation periods were required. The positive controls used were mitomycin 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. The number of cells with chromosomal aberrations and the number of total aberrations were calculated. Both in the absence and presence of metabolic activation, FPC-159 did not produce an increase in the number of cells with chromosomal aberrations.

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

In conclusion, FPC-159 is not considered clastogenic under the conditions of this assay.

9.4 Overall Assessment of Toxicological Data

The toxicity profile of FPC-159 indicated that it had low toxicity, with oral and dermal LD_{50} > 2000 mg/kg. No evidence of toxicity was observed in a 28-day repeat-dose toxicity study at doses up to 1000 mg/kg/day. However, the notified chemical produced mild eye irritation in rabbits and was a strong skin sensitiser in the guinea-pig.

FPC-159 was negative in both *in vitro* assays. Based on these results, PFC-159 could not be classified as mutagenic.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The ecotoxicity studies were conducted using FPC-159 (~ 89% purity) dissolved in water. The results in Table 2 were provided by the notifier and followed OECD guidelines. The results show the chemical to be non-toxic to aquatic and terrestrial fauna which is consistent with the water solubility and high molecular weight of the substance, and is also not expected to accumulate in sediment or to bioaccumulate. The surface activity of the dye did not appear to have any significant effect on aquatic organisms (i.e. bacteria, algae, fish and daphnids) under test conditions.

Table 2. Ecotoxicity test results

Species	Test	Result
Carp (*Cyprinus carpio*)	96 h acute	LC_{50} > 100 mg/L [a]
Water Flea (*Daphnia magna*)	48 h acute 21 d chronic	EC_{50} > 80 mg/L [b] EC_{50} (reproduction) > 100 mg/L [a]
Algae (*Scenedesmus subspicatus*)	72 h	For growth inhibition (0-72 h): E_BC_{50} > 70 mg/L [b] For growth rate reduction (0-72 h): E_RC_{50} > 70 mg/L [b]
Earthworm (*Eisenia foetida foetida*)	14 d acute	LC_{50} > 1000 mg/kg [c]
Activated Sludge	30 min	Respiration Inhibition Test: IC_{50} > 100 mg/L [c]

a. actual concentration b. exposure concentration (geometric mean of highest and lowest measured concentrations c. nominal concentration.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The greatest environmental exposure will be from disposal of spent processing solutions to sewer. Further dilution of the chemical would be achieved on entering the waste stream of the shopping complex that the photolab is part of, as well as dilution from the main sewer, giving a concentration in the low ppb range. As the concentration of the chemical is expected to be < 4 ppm (due to 1:>1500 dilution as described above) at the photolab outlet, which is already an order of magnitude below the lowest effect (algae growth inhibition or rate reduction), there is negligible hazard posed to the environment. Also, the chemical is not expected to accumulate in sediment or to bioaccumulate. The surface activity of the chemical did not appear to have any significant effect on aquatic organisms (i.e. bacteria, algae, fish and daphnids) under test conditions.

Conclusion

FPC-159 will be used as a whitener in film processing. It is very water soluble and the greatest environmental exposure is expected from disposal of spent processing solutions to sewer. Disposal will be according to industry guidelines, which refer to appropriate local regulations and also state that "photographic

chemical supply companies have the principle obligation for ensuring the photographic industry disposes of its wastes in the most environmentally sound manner". The concentration of FPC-159 at the photolab outlet is expected be about 4 ppm. The chemical shows negligible toxicity to aquatic and terrestrial fauna, and this, together with its expected low concentration in the waste stream and further dilution in the sewage system, suggests FPC-159 will pose a negligible hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical arrives in Australia as a 0.5% aqueous solution in 2.5 litre plastic sealed bottles with screw type plastic tops, packed into 4 bottle cartons, with the cartons palletised Occupational exposure during transport is unlikely to occur except in the event of an accident. Use of the notified chemical will be extensive, with eventually 560 photolabs and 40 other labs using the notified chemical over the next three years. With on average 3-5 staff in each lab, an estimated 3000 workers may be exposed to the notified chemical.

The main concern is the potential strong sensitisation caused by the chemical and also its possible eye irritancy potential. The main source of exposure is the process of the charging the developing machine by pouring in the contents of the plastic containers, which may produce spillage and splashing of the notified chemical. This will be minimised the wearing of protective clothing and eye protection. Since the film development occurs in a closed system, potential for exposure during this process is reduced. Photolabs usually have local ventilation to maintain a low level airborne concentration of fumes form the film development process.

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-159 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 (20) and AS 1716 (21),
  - impervious rubber gloves conforming to AS 2161 (22), and
  - long-sleeved work overalls conforming to AS 3765.2 (23)

. good work practices should be implemented to avoid generation of spray into non-work areas.

. good personal hygiene practices should be observed.

. container residues should be carefully emptied into the next to be used with the final container being capped for later use.

. 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-159 was provided in Worksafe Australia format (24).

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of FPC-159 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

If conditions of use are varied, greater exposure of the public to the product may occur. In such circumstances further information may be required to assess the hazards to public health.

16. REFERENCES

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17. OECD Guidelines for Testing of Chemicals - *Salmonella typhimurium*, Reverse Mutation Assay No. 471, 1983.

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