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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

CIN 10093872

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

CIN 10093872

1. APPLICANT

Kodak Australasia Pty Ltd of 173 Elizabeth St Coburg VIC 3058 has submitted a standard notification statement in support of their application for an assessment certificate for CIN 10093872.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of non-hazardous impurities, details of formulation of the notified chemical and details of exact import volume have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name:	CIN 10093872
Method of Detection and Determination:	can be detected by HPLC and characterised by UV/visible, infrared (IR) and ^{1}H nmr spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white solid
Melting Point:	123.8 – 126.4°C (OECD TG 102)
Boiling Point:	> 250°C (OECD TG 103)
Specific Gravity:	1.16 at 20°C (OECD TG 109)
Vapour Pressure:	≤ 2.4×10^{-5} kPa at 25°C (OECD TG 104) (see comments below)
Water Solubility:	< 0.004 mg/L at 21°C (OECD TG 105) (see comments below)

Particle Size:	Size Range (μm)	Mass %

< 1	2.4
1 – 2.5	1.4
2.5 – 5	2.2
5 – 7.5	3.1
7.5 – 10	2.9
10 – 20	19.9
20 – 30	28.1
30 – 40	20.8
40 – 50	10.9
50 – 60	6.4
60 – 70	1.0
> 70	0.8

12 % < 10 μm

Partition Co-efficient (n-octanol/water):	log P_{ow} > 6.2 at 20°C (OECD TG 117) (see comments below)
Fat Solubility:	17 – 21 g/kg at 37°C (OECD TG 116)
Surface Tension:	not surface active (OECD TG 115)
Hydrolysis as a Function of pH:	not determined (see comments below)
Adsorption/Desorption:	not determined (see comments below)
Dissociation Constant:	not determined (see comments below)
Flash Point:	not applicable for solids of low vapour pressure
Flammability Limits:	not highly flammable; combustible (84/449 EEC, A.10)
Autoignition Temperature:	no autoignition observed below melting point (126.4°C) (84/449 EEC, A.16)
Explosive Properties:	not explosive (84/449 EEC, A.14)
Reactivity/Stability:	not oxidising (84/449 EEC, A.17); expected to be stable under normal environmental conditions

Comments on Physico-Chemical Properties

The vapour pressure was determined using the static method in multiple measurements at the temperatures of 80.1, 90.1 and 100.1°C. From these measurements it was possible to estimate the latent heat of sublimation (ΔHsub= 56.45 kJ/mole), and then to use this parameter to extrapolate for the vapour pressure at 25°C using the Clausius–Clapeyron equation. The low result of 0.024 Pa is in accord with the relatively high molecular weight of this compound. However, it was noted during the tests that for a given vapour pressure measurement, the

measured pressure decreased with time, and this was not discussed in detail in the report. Since the new chemical contains around 2.3 % of lower molecular weight impurities (which may have higher vapour pressures than that of the new compound itself), the estimated vapour pressure of 0.024 Pa at 25°C is considered to be a maximum value.

Water solubility was determined using the flask method whereby the new compound was equilibrated with distilled water at 21°C, followed by quantitative measurement of the test compound in the saturated solution by High Performance Liquid Chromatography (HPLC). However, it was found that while possible to determine the presence of the compound in water, the size of the peak in the chromatogram was small, and below the quantitative detection limit of the equipment (< 4 μg/L).

No data on hydrolytic degradation was supplied with the notification as the very low water solubility of the compound prevented acquisition of accurate experimental data. However, the compound contains no bonds which are susceptible to hydrolysis in the environmental pH region of 4 < pH < 9, and so it is expected to be stable. The ester bonds may be susceptible to hydrolysis under extreme pH conditions.

Experimental determination of the n-octanol/water partition coefficient was made using the HPLC method. Using this technique, the retention time of the compound on a C18 column is compared with those for a series of standard compounds with known values for log P_{ow}. For the present study a series of ten reference compounds was used ranging from ethylmethyl ketone with log P_{ow} of 0.3, to 2,4-DDT with log P_{ow} of 6.2. The retention time of the new compound on the column exceeded that of the 2,4-DDT, and consequently indicated log P_{ow} for the compound is > 6.2.

Adsorption/desorption data was not provided, however the very low water solubility and high value for the partition coefficient indicates the new compound would strongly associate with the organic component of soils and sediments. The low water solubility indicates that once adsorbed to soil or sediments, the compound is unlikely to be mobile in these media.

The compound does not contain any highly acidic or basic groups capable of dissociating in water under normal environmental conditions.

The solubility of the compound in standard fat at 37°C was determined as being between 17 and 21 g/kg (after over-saturation). There was a high degree of variation in the results, possibly indicating that equilibrium had not been achieved. High values for Log P_{ow} often indicate that a compound has very high affinity for fat and a high solubility in this medium, but in the present case the fat solubility appears to be moderate.

The surface tension of a saturated water solution of the compound – prepared by stirring an excess of the compound with doubly distilled water over a 17 hour period, followed by centrifugation - was determined as 72.5 mN/m at 20°C. The very low water solubility (< 4 μg/L) precluded analytical determination of the actual solution concentration, but the measured surface tension of the solution was only slightly less than that measured for distilled water (73.7 mN/m). Therefore it was concluded that the new compound is not surface active.

Test reports on the determination of flammability, autoflammability, explosive properties and oxidising properties were provided by the notifier.

4. PURITY OF THE CHEMICAL

Degree of Purity:	97.2 %
Hazardous Impurities:	none identified
Non-hazardous Impurities (> 1% by weight):	identities of non-hazardous impurities have been exempted from publication in the Full Public Report
Additives/Adjuvants:	None

5. USE, VOLUME AND FORMULATION

The notified chemical will be used in the manufacture of photographic film and paper.

The notified chemical will not be manufactured in Australia. It will be imported in triple skinned plastic lined paper bags, each containing 10 kg of notified chemical. The import volume for the notified chemical is estimated to be approximately 20 tonnes per annum during the first five years of importation.

6. OCCUPATIONAL EXPOSURE

Transport and storage workers are not likely to be exposed to the notified chemical except in the case of an accident involving damage to the packaging.

The appropriate amount of the notified chemical, in powdered form, will be weighed and added to mix tanks with other substances to form gelatin dispersions, containing less than 10 % notified chemical, in multi-batch runs, once per week. The approximate volumes of the batches in mix tanks were not provided. The addition of the notified chemical will take approximately 4 minutes per batch. Dermal contact would be the main route of exposure for workers at the mix tank site. However, inhalation and eye exposure to the powdered form of the notified chemical may also occur because weighing and adding to the mix tank is an open process, and the notified chemical includes a significant proportion (12 %) of particles in the respirable size range while all particles are within the inspirable size range.

Weighing of the notified chemical and addition to the mix tank will be conducted under local exhaust ventilation. Workers handling the dry powder are to wear company provided overalls, safety glasses, disposable vinyl gloves, and a half face respirator with particle filter (during weighing) or disposable dust and particle masks (during addition to the mix tanks).

The notifier indicates that 12 operators will be involved in producing the gelatin dispersions.

The gelatin dispersion will be bagged and stored in a cold room up to several weeks prior to use. At the melt tank site, the gelatin dispersion and other ingredients will be added to melt tanks. The occupational exposure would predominantly be by dermal contact during the addition of gelatin dispersion into the melt tanks. Workers are to wear overalls, safety glasses

and gloves (as described above) during this process. The melt dispersion will then be pumped to automated processing equipment, where the notified chemical will be incorporated into photographic films and paper. Intermittent dermal exposure to the notified chemical is also possible during cleaning of automated processing equipment.

The notifier indicates that 16 operators and 4 laboratory technicians will be involved in handling and testing the gelatin dispersions.

After incorporation in end use articles, the notified chemical will be beneath several overcoat layers and will not be available for further exposure.

7. PUBLIC EXPOSURE

The notified chemical will be used only within an industrial environment prior to incorporation in photographic film and paper. These will be sold to the public and therefore there will be widespread availability of the notified chemical in the public domain in these forms. However, once incorporated onto photographic film or paper, the gelatin dispersion containing the notified chemical will reside beneath several overcoat layers, which limits the possibility of dermal contact.

8. ENVIRONMENTAL EXPOSURE

Release

Some chemical is likely to be left in the bags after they have been emptied. The company did not provide estimates of these residues, but if it is assumed that 0.5 % of the imported volume is left in the bags, this amounts to a release of around 100 kg per annum. The company also indicated that the notified chemical may be released in various process liquors, and that this would be released to the sewerage system, and discharged to the sea after treatment. The release is expected to total around 360 kg each year.

Most of the chemical is expected to be retained in the photographic emulsion, and would consequently be dispersed widely throughout Australia. Eventual disposal of old photographs and negatives is likely to be through deposition into landfill where very slow release could be expected as the old photographs and the emulsion become degraded. Some old photographs and negatives may be incinerated, which would destroy the chemical.

Fate

The notifier included a report on biodegradation of the new compound (Tanoue, 1989) performed according to the Modified MITI Test (OECD TG 302 C). In this test the compound was incubated with activated sludge at 25°C over a 28 day test period, and the rate of degradation followed by changes in the Biochemical Oxygen Demand (BOD) of the inoculum. The BOD measurements indicated that test compound (added to the inoculum at a level of 30 mg/L) was not degraded to any measurable extent after 28 days, while a reference test using 100 mg/L of aniline resulted in 75 % degradation after 14 days.

Supplementary analysis of the inoculum for the test chemical showed only 9 % loss of the chemical indicating that biodegradation under aerobic conditions is a very slow process. These results indicate that the compound is not biodegraded under aerobic conditions.

The very low water solubility and high value for the n-octanol/water partition coefficient indicate that, once released to the water compartment, the compound would very likely become strongly associated with aquatic sediments. While the compound is not biodegradable under aerobic conditions, once adsorbed into aquatic sediments it may be slowly degraded through various slow biological and abiotic processes operative in anaerobic environments. The degradation products are likely to be water, methane and oxides of carbon. Any material disposed of into landfill (eg residues in empty bags) is also expected to become associated with the organic component of soils, and may also be slowly degraded over time.

However, in the absence of additional test data on biodegradation rates under both aerobic and anaerobic conditions, the available data indicate that, once released, the compound is likely to be persistent in the environment. This may have implications for bioaccumulation potential.

Old photographs and film negatives which are discarded would most probably be placed into landfill where the chemical is expected to be slowly released as the film and emulsion are degraded. It is expected that released compound would become associated with the organic component of the soil, and would be slowly destroyed as indicated above. Some old photographs and negatives may be incinerated which would result in complete destruction of the compound with formation of water and carbon dioxide.

The company submitted a report on the bioaccumulation potential of the new chemical in the fatty tissue of carp (*Cyprinus carpio*), which was conducted according to the protocol of a Japanese MITI test (Tanoue, 1999). The fish were placed in a tank through which the new chemical was circulated at a nominal concentration of 2.8 mg/L. Due to the very low water solubility of the test compound (< 4 µg/L at 21°C), dispersion of compound in water was assisted by admixture with polyoxyethylene hydrogenated castor oil (HCO-40). This dispersant was present at around 10 times the concentration of the test material. The test was run over an eight week period during which time the measured lipid content of the fish was between 2.8 % and 6.7 % by weight.

Throughout the 8 week test period, the level of new compound in the fatty tissue of the fish was below the detection limit of the analytical procedure (0.015 mg/kg of fatty tissue). Consequently, it was concluded that the bioconcentration factor for the new compound was < 0.66.

The test described here is for “high exposure” conditions where the nominal level of the test substance in the water was 2.8 mg/L. The investigators also conducted tests under “low exposure” conditions with a nominal level of the new chemical of 0.28 mg/L. The bioconcentration factor under these conditions was established as < 6.6. Again, no better quantification of this was possible due to limitations of the analytical procedure.

The compound has very low water solubility, a large value for the n-octanol/water partition coefficient, and a moderate fat solubility. Also, the compound is not susceptible to rapid biodegradation, and according to Connell (Connell, 1990), this combination of physico-chemical attributes gives chemicals a high potential for bioaccumulation. However, Connell

also points out molecular weight is also important, and that compounds having molecular weights in excess of 600 g/mol have attenuated potential for bioaccumulation. The present compound has a molecular weight of 741 g/mol, and this presumably mitigates the potential for bioaccumulation.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of CIN 10093872

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5000 mg/kg	(Sako, 1990b)
acute dermal toxicity	rat	LD_{50} > 2000 mg/kg	(Daamen, 1991), (Sako, 1990a)
skin irritation	rabbit	non-irritating	(Chazono, 1986)
eye irritation	rabbit	slightly irritating	(Chazono, 1986)
skin sensitisation	guinea pig	non sensitising	(Nakanishi, 1990)

9.1.1 Oral Toxicity (Sako, 1990b)

Species/strain:	rat/Sprague Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage; test substance suspended in 0.5% methylcellulose, 500 mg/mL
Test method:	EPA (1982) Health Effects Test Guidelines (TSCA). EPA Report, EPA 560/6 82-001 – limit test
Mortality:	no deaths recorded over the observation period
Clinical observations:	no clinical signs noted
Morphological findings:	uterine horn of one female was distended with fluid
Comment:	no difference noted between body weights of treated and control groups
LD_{50}:	> 5000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2a Dermal Toxicity (Daamen, 1991)

Species/strain:	rat/Wistar
Number/sex of animals:	5/sex/group, 3 test groups
Observation period:	14 days
Method of administration:	single 500, 1000 and 2000 mg/kg occlusive application of test substance in propylene glycol for 24 hours
Test method:	OECD TG 402
Mortality:	four males at the high dose of 2000 mg/kg died within 24 hours after application; post mortem examination of these animals did not reveal any abnormalities
Clinical observations:	all surviving animals had signs of lethargy post treatment, resolving by day 5 oedema was noted on the treated skin of the surviving male dosed at 2000 mg/kg at bandage removal; the majority of animals dosed at 1000 or 500 mg/kg showed scaliness and some females also had erythema between days 5 and 8
Comment:	one female dosed at 2000 mg/kg showed body weight loss while the majority of animals showed lower than expected body weight gain over the first week of the study; the majority showed improved body weight gain over the second week of the study
LD_{50}:	due to the mortality distribution only estimated dermal LD_{50} values could be calculated; these were 2478 mg/kg body weight for the sexes combined and 1533 mg/kg body weight for the males alone; the LD_{50} for the combined sexes can be considered to be > 2000 mg/kg
Result:	the notified chemical was of low dermal toxicity in rats

9.1.2b Dermal Toxicity (Sako, 1990a)

Species/strain:	rat/Sprague Dawley
Number/sex of animals:	5/sex
Observation period:	14 days

Method of administration:	dorsal application of test substance suspended in 0.5% methylcellulose for 24 hours under occlusive conditions
Test method:	EPA (1982) Health Effects Test Guidelines (TSCA). EPA Report, EPA 560/6 82-001 – limit test
Mortality:	no animals died over the observation period
Clinical observations:	no adverse signs were noted
Comment:	there were no differences in mean body weights between treated and control groups; at necropsy, three females had fluid-distended uterine horns
LD_{50}*:*	> 2000 mg/kg
Result:	the notified chemical was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

The notifier did not submit an inhalation toxicity study report.

9.1.4 Skin Irritation (Chazono, 1986)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/sex
Observation period:	3 days
Method of administration:	application sites were prepared by clipping a right and left area with respect to the midline on the back of the animals. One of the sites was abraded with an 18-G needle to selectively destroy the stratum corneum without injuring the dermis or causing haemorrhage. 0.5 g of test substance, moistened in saline, was applied to both sites under occlusive dressing for 4 hours
Test method:	EPA Guidelines, 1982
Comment:	observation at 4.5, 24, 48 and 72 hours after application of test substance revealed no local reactions, such as erythema and oedema, on either the abraded or intact sites; all Draize scores were zero
Result:	the notified chemical was non-irritating to the skin of rabbits

9.1.5 Eye Irritation (Chazono, 1986)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3/sex

Observation period: 3 days

Method of administration: 0.1 gm of test substance was placed in the conjunctival sac of the eye and lids were held shut for 1 second; the contralateral eye served as control.

Test method: EPA Guidelines, 1982

Draize scores ( ) of unirrigated eyes:

	Time after instillation											
Animal	***1 day***			***2 days***			***3 days***			***4 days***		
Cornea	all Draize scores were zero											
Iris	all Draize scores were zero											
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1[1]	0	0	1	0	0	0	0	0	0	0	0
2	1	1	0	0	0	0	0	0	0	0	0	0
3	1	1	0	0	0	0	0	0	0	0	0	0
4	1	1	0	0	0	0	0	0	0	0	0	0
5	1	0	0	0	0	0	0	0	0	0	0	0
6	1	0	0	0	0	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge

Comment:

group mean scores:
corneal opacity: 0
irideal lesions: 0
conjunctival redness: 0.055
conjunctival chemosis: 0

one hour after application, conjunctival redness was seen in all animals and chemosis in three animals; After 24 hours, only one animal had signs of redness; by 48 hours, all ocular lesions had disappeared

Result: the notified chemical was slightly irritating to the eyes of rabbits

9.1.6 Skin Sensitisation (Nakanishi, 1990)

Species/strain:	guinea pig/Hartley
Number of animals:	40 males
Induction procedure:	day 1 each of the following materials was intradermally injected to the left and right sides of a prepared site on the animals' backs at the rate of 0.05 mL/site 1. 1:1 (v/v) Freunds Complete Adjuvant (FCA):water 2. 5.0% solution of test substance in corn oil 3. 1:1 (v/v) 10% solution of test substance in FCA and water day 8 a lint patch saturated with 0.4 gm of 25% test substance in petrolatum was applied to the test site for 48 hours under occlusion
Challenge procedure:	day 22 a lint patch saturated with 0.2 gm of 25% test substance was applied topically to the flank for 24 hours
Test method:	OECD TG 406; Magnusson and Kligman maximisation test
Comment:	no appreciable skin reactions were observed either 24 or 48 after challenge application; the positive control treated animals produced appropriate responses.
Result:	the notified chemical was non-sensitising to the skin of guinea pigs

9.2a 28-day Repeated Dose Oral Toxicity (Shibata, 1990b)

Species/strain:	Rat/Sprague Dawley Crj:CD (SD)
Number/sex of animals:	6/sex/group; 5 groups
Method of administration:	diet *ad libitum*
Dose/Study duration:	0, 1000, 3000, 10000 and 30000 ppm/28days female: 0, 102.5, 357.1, 1626.5, 4953.7 mg/kg/day male: 0, 99.8, 251.9, 903.5, 2468.2 mg/kg/day
Test method:	not stated

Clinical observations:
During week 1, one male animal treated with 30000 ppm demonstrated head tilt and

emaciation, and was killed in a moribund condition during week 2. The cause was found to be hydrocephalus.

No significant differences in body weight changes between treated and controls were noted throughout the study. A slight decrease in food consumption was noted for females at 1000 and 3000 ppm, but no significant difference from controls was observed at the higher doses.

Urinalysis
Increased urinary protein levels were recorded in two females at 30000 ppm and one male in each of the groups at 3000, 10000 and 30000 ppm. Very slight occult blood was noted in one male at 10,000 ppm.

Haematology
Platelet numbers were significantly elevated in males at 30000 ppm. Differential counts in white blood cells revealed a decrease in segmented neutrophils in males at 3000 and 30000 ppm, and monocytes were decreased in males at 10000 ppm. An increase in lymphocytes was observed in males at 3000 and 30000 ppm.

Clinical Chemistry
Total bilirubin levels were statistically increased in females at 1000 and 30000 ppm, but the change was slight and not dose-dependent.

Total cholesterol levels were statistically increased in females at 1000 ppm and above and males at 10000 and 30000 ppm. Elevated phospholipid levels were recorded in females at 1000 ppm and above and in males at 30,000 ppm. While increases in these parameters were not dose-dependent in females at 1000 ppm and above, the ranges were approximately 35 - 54 % and 33 – 50 % higher, respectively. As similar changes were observed in males, changes in these two parameters appeared to be clearly related to treatment with the test substance.

Statistically decreased blood urea nitrogen (BUN) levels in both sexes at 30000 ppm and increased albumin levels in females at 30000 ppm were noted.

Significant variations in glutamic pyruvic transaminase (GPT) and K^+ levels and the Na/K ratio were observed, however, they were seen only at intermediate dose levels.

Gross pathology:
Discolouration of the lungs and white material in the urinary bladder lumina was observed for some animals. However, this included control animals and no observations were made at high dose levels, so the observations were probably not treatment related.

Organ weights:
At necropsy, females at 10,000 ppm and above had higher absolute liver weights, with relative liver weights elevated at 3000 ppm and above. In males, increased absolute liver weights were seen at 3000 and 30000 ppm and increased relative liver weights at 1000 ppm and above.

Relative kidney weights were increased in females at 3000 ppm and above and in males at 1000 and 10000 ppm. Absolute pituitary weights were higher in males at 30000 ppm than

in controls. Both absolute and relative weights of the thyroids were increased in males at 10000 ppm only.

Histopathology:
No histopathological examinations were conducted.

Comment:
Considerable changes in organ weights and clinical chemistry parameters were observed in the feeding study. Statistically significant increases in total cholesterol and phospholipid levels in serum were observed in both sexes at a number of doses and appeared to be treatment related. Other changes in clinical chemistry changes were noted, for example, total bilirubin, blood urea nitrogen and albumin, however, as these changes were either slight, not dose-dependent or occurred in only one sex, insufficient evidence is available to determine whether the changes were treatment related.

Statistically significant increases in relative liver and kidney weights were observed in both sexes and, although some of the changes were not strictly dose-dependent, for example, relative kidney weights in males, they were considered to be treatment related. Other organ weight changes were confined to males only and were considered inconclusive.

This study was designed to determine dosage levels in a 13-week (subchronic) oral toxicity study, as reported in section 9.2b.

Result:
Based on increases in relative liver weight and total cholesterol in serum at the lowest dose, 1000 ppm (101.1 mg/kg/day average for both sexes), a No Observed Adverse Effect Level (NOAEL) could not be established in the study.

9.2b 90-day Repeated Dose Oral Toxicity (Shibata, 1990a)

Species/strain:	Rat/Sprague Dawley Crj:CD
Number/sex of animals:	20/sex/group; 5 groups
Method of administration:	diet *ad libitum*
Dose/Study duration:	0, 100, 1000, 10000 and 30000 ppm/13 weeks female: 0, 11.18, 105.2, 1191.5, 3344.8 mg/kg/day male: 0, 7.85, 74.2, 796.1, 2221.2 mg/kg/day 10 animals of each group were sacrificed at 6 weeks and the remaining animals at 13 weeks
Test method:	not stated

Clinical observations:
Clinical observations did not reveal any abnormalities except that one male rat at 30000 ppm had a cataract. No deaths were recorded during the study.

Increased body weight gain was noted in females at 30000 ppm at weeks 8 and 12, and a slight increase in water consumption was noted in males at 30000 ppm from week 7; no other significant observations were made.

Urinalysis
Very slight to marked occult blood was noted in occasional animals across all groups at both observation times.

Haematology
Platelet numbers were significantly elevated in males at 10000 ppm at 6 weeks. Differential counts in white blood cells revealed an increase in segmented neutrophils in males at 1000 ppm at 6 weeks, and monocytes were decreased in males at 10000 and 30000 ppm at 6 weeks and 13 weeks. An increase in eosinophils was observed in females at 1000 and 30000 ppm at 6 weeks. A decrease in lymphocytes was observed for males at 1000 ppm at 6 weeks, and an increase in lymphocytes was observed for males at 1000 ppm and females at 10000 ppm at 13 weeks.

Decreased haemoglobin was observed in 30000 ppm males at 6 weeks and 30000 ppm females at 13 weeks; mean corpuscular haemoglobin was decreased in 30000 ppm females at 13 weeks, and mean corpuscular volumes were decreased for 1000 ppm and 30000 ppm males at both 6 weeks and 13 weeks. Decreased haemocrit was observed for 30000 ppm males at 6 weeks.

Clinical chemistry
Increased GPT was observed in males at 1000 ppm and above at 6 weeks, and in males at 100 and 1000 ppm at 13 weeks. Total bilirubin was increased in females at 100 ppm and above at 6 weeks and in females at 10000 ppm at 13 weeks. Elevated total cholesterol was seen for both sexes at 1000 ppm and above at both observation times. Increased phospholipid levels were seen for both sexes at 1000 ppm and above at 6 weeks, and males at 1000 ppm and above and females at 1000 and 30000 ppm at 13 weeks. Triglyceride levels were increased in females at 1000 ppm and above at 13 weeks. Increased glucose was seen for females at 100, 1000 and 10000 ppm at 13 weeks, and decreased glucose was seen for females at 10000 ppm at 6 weeks.

An increase in total protein was seen for both sexes at 10000 and 30000 ppm at 6 weeks. A decrease in the albumin/globulin ratio was seen for 10000 ppm males at 6 weeks and 1000 and 10000 ppm males at 13 weeks. BUN levels were increased for females at 30000 ppm and decreased for males at 10000 ppm at 13 weeks. Alkaline phosphatase (ALP) was increased for females at 100 ppm and above, and decreased in males at 1000 and 10000 ppm at 13 weeks. Leucine aminopeptidase (LAP) levels were decreased in males at 1000 and 10000 ppm, and creatinine levels were decreased for females at 1000 ppm at 13 weeks.

An elevated Na/K ratio was seen for males at 30000 ppm at 13 weeks. Decreased sodium was seen for females at 100, 1000 and 30000 ppm at 13 weeks. Decreased potassium was seen for females at 100, 1000 and 30000 ppm and males at 100 and 30000 ppm at 13 weeks, but increased potassium was seen for males at 100 and 10000 ppm at 6 weeks.

Gross pathology:
Discolouration of the lungs and white material in the urinary bladder lumen was observed for some animals, including in the control group. Other observations were generally single

occurrences.

Organ Weights:
The absolute liver weight was increased in 30,000 ppm females and 10,000 ppm and above males at 6 weeks, and in both sexes at 1000 ppm and above at 13 weeks; the relative liver weight was increased in 1000 ppm and above females and in 10,000 ppm and above males at 6 weeks and females at 100 ppm and above and males at 1000 ppm and above at 13 weeks. The absolute kidney weight was increased in males at 100 ppm and above and females at 10000 ppm at 6 weeks, and in males at 1000 ppm and above and females at 100 ppm and above at 13 weeks; the relative kidney weight was increased in both sexes at 100 ppm and above at 6 weeks and both sexes at 1000 ppm and above at 13 weeks.

Changes in the absolute and/or relative weights of the brain, lung, heart, pituitary, thyroid and adrenal glands were seen for several groups but did not appear to be dose dependent.

Histopathology:
Histopathological studies were performed on the controls and 30000 ppm group after 13 weeks. Most observations were limited to occasional occurrences, although lesions of the lung, thyroid and prostate occurred in a number of animals, both control and treated.

Comment:
Many of the observed changes were slight, or did not show dose dependence, particularly for some clinical chemistry parameters. However, a number of the changes appeared to be treatment related, including changes in cholesterol, phospholipid and triglyceride levels, and in absolute and relative liver and kidney weights. All of these changes were observed at 1000 ppm and above. Some changes were also observed at 100 ppm. These parameters were also noted to have changed in the 28-day feeding study.

Result:
Based on the statistically significant and dose related changes in liver and kidney weights and some clinical chemistry parameters (cholesterol and phospholipid levels) at 1000 ppm in both sexes, the NOAEL was 100 ppm for both sexes (females: 11.18 mg/kg/day; males: 7.85 mg/kg/day). A No Observed Effect Level (NOEL) could not be established because of liver and kidney weight changes in females at 100 ppm.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Kogiso, 1991)

Strains:	*Salmonella typhimurium* TA1535, TA1537, TA1538, TA98 and TA100
Concentration range:	5, 15, 50, 150, 500, 1500 and 5000 μg/plate, dissolved in DMSO
Metabolic activation:	10% rat liver S9 fraction (Aroclor 1254-induced) in standard cofactors

Positive controls:	TA98 + S9: 5 μg/plate benzo[a]pyrene TA98 – S9: 0.1μg/plate 2-(2-furyl)-3-(5-nitro-2-furyl) acrylamide TA100 + S9: 5 μg/plate benzo[a]pyrene TA100 – S9: 0.01μg/plate 2-(2-furyl)-3-(5-nitro-2-furyl) acrylamide TA1535 +S9: 2 μg/plate 2-aminoanthracene TA1535 – S9: 0.5 μg/plate sodium azide TA1537 + S9: 5 μg/plate benzo[a]pyrene TA1537 – S9: 80 μg/plate 9-aminoacridine TA1538 + S9: 5 μg/plate benzo[a]pyrene TA1538 – S9: 2 μg/plate 2-nitrofluorene
Test method:	not stated, similar to OECD TG 471
Comment:	no appreciable toxicity was observed at the highest test concentration of 5000 μg/plate; precipitation of the test substance was seen at 500 μg/plate and higher, but did not interfere with the validity of the test; all concentrations were tested in triplicate and each test was conducted twice under the conditions of the study, the notified chemical caused no substantial increases in revertant colony numbers over control counts at any concentration in either the presence or absence of the rat liver microsomal enzymes all positive and negative controls responded appropriately
Result:	the notified chemical was non-mutagenic under the conditions of the assay

9.3.2 HPRT forward mutation assay in V79 Chinese hamster cells *in vitro* (van de Waart, 1991)

Cells:	V79 Chinese hamster cells
Metabolic activation system:	10% rat liver S9 fraction (Aroclor 1254-induced) in standard cofactors
Positive controls:	with S9: 8 mM dimethylnitrosamine in HBSS without S9: 6 mM ethylmethanesulfonate in DMSO
Doses:	test concentrations: 5, 10, 25 and 50 μg/mL, dissolved in ethanol

Test method:	OECD TG 476
Comment:	the test substance did not induce a significant dose-related increase in the mutant frequency at the HPRT-locus in both independent experiments, either in the presence or absence of S9 slight toxicity was observed at the highest dose, with or without S9, however, the cloning efficiency was not affected all positive and negative controls responded appropriately.
Result:	the notified chemical was not mutagenic in the V79/HPRT mutation test under the experimental conditions described.

9.3.3 Chromosomal Aberrations in Chinese Hamster Ovary (CHO) Cells *In Vitro* (Kogiso, 1992)

Cells:	Chinese Hamster Ovary (CHO-K1)
Doses:	test material 0.3-150 μg/mL (with or without metabolic activation) positive controls Mitomycin C (MMC) 0.2, 2 μg/mL (without metabolic activation) cyclophosphamide (CPA) 50, 150 μg/mL (with metabolic activation)
Metabolic Activation System:	rat liver S9 fraction from animals pretreated with Kanechlor-400
Test method:	not stated, similar to OECD TG 473
Treatment Regime:	with metabolic activation: test material or positive control added to cell cultures in serum free medium, with 100 μL/mL S9 mix, for 2 hours; the cells were then washed and cultured in fresh complete medium to a total time of 10 or 18 hours without metabolic activation: test material or positive control added to cell cultures in complete medium for a total time of 10 or 18 hours without a change of medium colcemid was added to all cultures 2 hours before harvest to arrest cells in metaphase

Observations:	in a preliminary cytotoxicity assay, neither cell cycle delay nor severe cytotoxicity were observed at any concentration with or without metabolic activation; a reduction in mitotic index from 6.6 % to 3 % was observed in the absence of metabolic activation for 150 μg/mL; precipitation was for concentrations of 50 μg/mL and above no significant increases in the total number of aberrations or the frequency of cells with structural aberrations were observed in the presence or absence of metabolic activation statistically significant increases in cells showing structural chromosome aberrations occurred for the positive control substances, indicating that the test system responded appropriately
Results:	the notified substance did not induce structural chromosome aberrations in the presence or absence of metabolic activation

9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity (LD_{50} > 5000 mg/kg) and low acute dermal toxicity (LD_{50} > 2000 mg/kg) in rats. It was non-irritating to rabbit skin but produced slight signs of irritation in the rabbit eye. There was no evidence of skin sensitising capacity in a guinea pig maximisation test. An inhalation study was not undertaken.

In genotoxicity studies, the notified chemical was not mutagenic in bacteria, nor did it induce an increased frequency of mutations in the HPRT assay in V79 Chinese hamster cells.

A four week oral toxicity study in rats produced a number of findings considered to be treatment-related. These were mainly concerned with clinical chemistry parameters and increased liver and kidney weights. Because these were present even at the lowest test dose of 1000 ppm, a NOAEL could not be established. A 90-day oral toxicity study essentially confirmed the clinical chemistry and organ weight findings of the four week study. A NOAEL of 7.85 mg/kg/day for males and 11.18 mg/kg/day for females was established. No NOEL could be established as changes in kidney and liver weights were seen in females at 11.18 mg/kg/day. The effects observed at higher concentrations would not be regarded as "severe lesions", and so, according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), classification with the risk phrase R48 is not warranted.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Test	*Species*	*Results (nominal)*
Acute Toxicity to Fish [OECD TG 203]	Zebra fish *Oncorhynchus mykiss*	LC_{50} (96 h) > 4 µg/L (see notes below)
Acute Immobilisation to Fresh water invertebrates [OECD TG 202]	*Daphnia magna*	EC_{50} (48 h) > 4 µg/L (see notes below)
Inhibition of Algal growth [OECD TG 201]	*Selenastrum capricornutum*	E_bC_{50} (72 h) > 330 µg/L (see notes below)
Respiration Inhibition of Activated Sludge Bacteria [OECD TG 209]	Activated sludge bacteria	EC_{50} (3h) > 100 mg/L (see notes below)

Fish
Due to the very low water solubility of the test compound (<4 µg/L – see physico-chemical properties above), a limit test only could be conducted (Bogers, 1991a). Three replicate vessels were filled with water containing a nominal 1000 mg/L of the test compound, together with a dispersal aid (Cremophor RH40).

These vessels were stirred for 70 hours in order produce saturated solutions of the test compound. The test media prepared in this manner were cloudy, indicating incomplete dispersion. Nevertheless, these solutions were used for the tests. Following preparation of the test media, 10 zebra fish were added to each of the three vessels, and the general health of these animals monitored over a four day (96 hour) period. As a control, ten fish were also placed in a separate test vessel to which no test compound had been added. Temperature was maintained at 22.5±0.5°C, and pH and dissolved oxygen levels were between 7.5 and 8.2 and always greater than 5 mg/L respectively.

No mortality or aberrant behaviour was observed in any of the thirty test specimens or in the control fish. From these observations, it was concluded that the new compound is not toxic to this species up to the limits of its water solubility. In support of this conclusion, no mortality or aberrant behaviour was observed over an 8 week period among the fish (carp) specimens used in the tests for bioconcentration described above.

Invertebrates
An acute toxicity test of new chemical against *Daphnia magna* was conducted using a static methodology (Bogers, 1991b). As with the fish test, the media was made up by stirring the test material into water at a nominal loading of around 1000 mg/L, together with the dispersant Cremophor RH40 added at 107 mg/L. Stirring was continued over a 48 hour period, and the resulting mixture used for the tests. Some of the water was filtered, and this filtered water (still slightly turbid) then used for additional tests.

Ten daphnia were placed in duplicate test vessels each containing 100 mL of the test media (either filtered or unfiltered), and for control purposes ten animals were placed in vessels containing only water. In a separate vessel, water containing (nominally) 100 mg/L of the Cremophor RH40 dispersant was used as an additional control. The general behaviour of the animals in the test and control vessels was monitored over a 48 hour test period. Temperature was maintained between 18 and 19.5°C, and pH and dissolved oxygen levels were between 8.0 and 8.2, and always greater than 5 mg/L, respectively.

Although two daphnia (10 % of the test population) were immobilised after 48 hours exposure to the filtered test media, one of the control animals was also immobilised, as well as one in the unfiltered test medium. These levels of immobilisation were not considered significant, and consequently it was concluded that the new compound is not toxic to daphnia up to the limits of its water solubility.

A reference test to confirm the sensitivity of the test system was conducted using potassium dichromate solutions. This reference tested indicated the 48 hour EC_{50} for this compound to be 0.87 mg/L, which is within the expected range of 0.6-1.9 mg/L.

Algae
As with the fish and daphnia tests, the low solubility of the test compound in water meant the test media had to be prepared using assistance from other materials. In the present case, the tests on algal growth inhibition were performed with solutions of the new compound made up in nutrient media at nominal loadings of 0, 30, 60, 100, 180 and 330 µg/L with the assistance of dimethyl sulphoxide (DMSO) to assist uniform dispersion (Bogers, 1995). The tests were conducted over a 72 hour period using three replicates for each test concentration, and six replicates for the blank and solvent control (water containing DMSO).

No inhibition of the algal growth was observed for either the control, solvent control or any of the test media. From the results of this test it was concluded that the new compound is not toxic to this species of green algae (*Selenastrum capricornutum*) up to the limits of its water solubility.

Sewage Bacteria
The test substance was suspended in artificial sewage at a nominal loading of 100 mg/L using the surfactant Tween 80 to assist homogeneous suspension of the material (Desmares-Koopmans, 1995). This media was added to activated sludge, and duplicate samples were aerated for 30 minutes, and then poured into 300 mL bottles fitted with oxygen sensing electrodes. The rate of oxygen consumption was measured for both replicates, and compared with that in a control vessel. Neither of the replicates indicated any significant inhibition of bacterial respiration compared with the controls, and it was concluded that the new chemical is not toxic to sewage bacteria up to the limits of its water solubility.

In contrast to tests with the new chemical, a reference test conducted with 3,5-dichlorophenol inhibited bacterial respiration by 28 % at a concentration of 3.2 mg/L, and 88 % at 32 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The new chemical is not considered to pose a hazard to the environment when used as a component of photographic emulsions in the manner indicated by the company.

As a result of the disposal of industrial wastes from the production of photographic emulsion, it is estimated that up to 360 kg of the chemical could be released into the Melbourne sewage system each year.

Total influent to the Werribee sewage treatment plant is around 500,000,000 litres per day (1.8×10^9 L per year), and consequently the Predicted Environmental Concentration (PEC) of the compound in the sewage is then 360 (kg)/180×10^9 (L) = 2 µg/L.

The chemical is not toxic to those species of fish, daphnia or algae against which it has been tested up to the limits of its water solubility. However, it should be noted that the water solubility may be only slightly greater than the PEC value. Similarly, the new compound does not inhibit the respiration of sewage bacteria.

Due to the low water solubility and high value for the n-octanol/water partition coefficient, most of the chemical released to the sewer in this manner is expected to become associated with the aquatic sediments. However, the compound may be persistent in the environment, as discussed below, and so its concentration in the sewer sediments may increase with time. However, no allowance for the effects of possible dispersion processes has been made during this assessment.

The chemical is not readily biodegradable, and neither is it susceptible to chemical hydrolysis, and, once released, it may persist in the environment. However, despite the low water solubility (< 4 μg/L) and high value for log P_{ow} (> 6.2), the chemical has been shown to have low potential for bioaccumulation (BCF< 6.6) using a Japanese MITI test protocol.

A further 100 kg per year of the compound is expected to remain as unused residuals in the empty bags, which are expected to be placed into landfill. Chemical released from the bags as they degrade will become associated with the organic component of soils and sediments, and is not expected to be mobile in these media.

Most of the chemical is expected to be retained in the photographic emulsions of film negatives and photographs, which are likely to be eventually discarded into landfill. Here the chemical is expected to be slowly released as the photographs degrade, and will then become associated with the organic component of soils. Some old photographs may be incinerated which will completely destroy the compound with production of water vapour and oxides of carbon.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical does not meet the criteria for classification as a hazardous substance according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

The acute oral toxicity of CIN 10093872 is very low (LD_{50} > 5000 mg/kg); the acute dermal toxicity is low (LD_{50} > 2000 mg/kg), although deaths were observed among male rats at the highest dose tested of 2000 mg/kg. It is not an irritant to the skin of rabbits, but is a slight irritant to rabbit eyes. It was not a skin sensitiser in guinea pigs in an adjuvant type test. No evidence of genotoxicity was observed in three *in vitro* genotoxicity tests.

For longer-term systemic effects, the NOAEL was found to be 100 ppm (7.85 mg/kg/day for males and 11.18 mg/kg/day for females) in a 90 day feeding study. The NOAEL was based on clinical biochemistry changes observed at 1000 ppm, along with increased liver and kidney weights. As changes in liver and kidney weight were observed in females at 100 ppm, with no corresponding clinical biochemistry changes, no NOEL can be established. Similar results were found in a 28 day study, but no NOAEL was established as effects were observed at the minimum dose level of 1000 ppm.

The results of the dermal toxicity study indicate that dermal absorption occurs to a significant effect, and therefore long term exposure by the dermal route with possible effects on the liver and kidney is likely to be one of the main potential hazards in the handling of the notified chemical. The major hazard from acute exposure arises from the eye irritant effects.

Occupational Health and Safety
Occupational exposure to the notified chemical can be divided into exposure to the powdered solid, the gelatin dispersions, and the finished photographic film and paper. The dust includes a significant proportion (12 %) in the respirable range, and is all within the inspirable range, and therefore will be a potential hazard by inhalation and by dermal and ocular exposure. Workers will handle the powdered solid for short periods during weighing and addition to the mix tanks where the gelatin dispersion is produced. Exposure may occur a large number of times throughout the year. Therefore, there is a risk of eye irritation on acute exposure to the chemical, and some risk of chronic effects on the liver and kidney arising from absorption of the chemical after dermal or inhalation exposure.

The risk of adverse health effects will be reduced by local exhaust ventilation during the processes which involve handling the powdered solid. The wearing of overalls, protective gloves, glasses and respiratory protection while weighing and mixing the powdered solid will also be required.

The handling of the gelatin dispersions, containing less than 10 % notified chemical, is a potential hazard by dermal exposure. Repeated exposure may lead to chronic effects on the liver and kidney from skin absorption. Standard procedures require the use of gloves, overalls and protective glasses by workers handling the gelatin dispersions. After incorporation in articles, the potential hazard should be negligible as the notified chemical will be beneath several overcoat layers.

Public Health
Photographic film and/or paper containing the notified chemical will be sold to the public; consequently there will be widespread availability in the public domain. Once incorporated onto photographic film and paper, the gelatin dispersion containing the notified chemical will reside beneath several overcoat layers, which limits the possibility of dermal contact. Consequently the potential for public exposure to the notified chemical during all phases of its life cycle is considered to be low and the notified chemical is not expected to pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to CIN 10093872 the following guidelines and precautions should be observed:

- Local exhaust ventilation should be provided in areas where the powdered solid is handled; respiratory protection should be selected and fitted in accordance with Australian Standard (AS) 1715 (Standards Australia/Standards New Zealand, 1994a) to comply with Australian/New Zealand Standard (AS/NZS) 1716 (Standards Australia/Standards New Zealand, 1994b);

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.2 (Standards Australia, 1990); impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994c);

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion;

- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical may 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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Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	3 severe	Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe