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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

CIN 10095204

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

CIN 10095204

1. APPLICANT

Kodak Australasia Pty Ltd of 173 Elizabeth Street COBURG VIC 3058 has submitted a standard notification statement in support of their application for an assessment certificate for CIN 10095204.

2. IDENTITY OF THE CHEMICAL

CIN 10095204 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, spectral data, and use have been exempted from publication in the Full Public Report and the Summary Report.

Trade Name:	CIN 10095204
Molecular Weight:	382.59
Method of Detection and Determination:	Infrared (IR), UV-visible, Nuclear Magnetic Resonance (NMR)
Spectral Data:	the notifier supplied IR, UV/Visible and ^{1}H NMR spectrometric data for the identification of the notified chemical

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white solid
Melting Point:	103.37°C
Density:	1 110 $kg.m^{-3}$
Vapour Pressure:	2.5 X 10^{-8} kPa at 25°C
Water Solubility:	< 5 $\mu g.L^{-1}$ at 23.7°C
Partition Co-efficient (n-octanol/water):	log $K_{ow} \cong 5.86$

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)
Surface Activity:	70.8 $mN.m^{-1}$ at 20°C
Particle Size:	38 - > 2 360 μm
Flash Point:	not applicable
Flammability:	not flammable
Autoignition Temperature:	not autoflammable
Explosive Properties:	not explosive
Reactivity/Stability:	not considered to possess oxidising properties

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines using facilities complying with OECD Principles of Good Laboratory Practice.

Preliminary testing determined that the water solubility was lower than the limit of detection for the column elution procedure, < 0.05 $mg.L^{-1}$ (50 ppb). An additional test, with samples analysed by HPLC/UV, estimated the water solubility of the notified chemical to be < 5 $\mu g.L^{-1}$ (5 ppb).

An attempt was made to measure the hydrolysis of the notified chemical at pH 4, 7 and 9, with test mixtures prepared using a cosolvent (1% acetonitrile). However, as water solubilities were at or below detection limits, the chemical could not be tested. Any hydrolysis of the ester functionality would be precluded by the very low water solubility.

Based on the high value of the partition coefficient the notified chemical is expected to adsorb strongly to soil/sediment.

Determination of a dissociation constant was attempted using OECD Test Guideline 112. Dissociation constant could not be determined by potentiometric titration due to the low solubility of the notified chemical in water (acidified, neutral and basic) and organic solvents (methanol, tetrahydrofuran, 2-propanol, acetonitrile or acetone). However, some dissociation of the hindered phenol is expected under strong alkaline conditions.
The notified chemical is not expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 $mN.m^{-1}$ (European Economic Community (EEC), 1992).

4. PURITY OF THE CHEMICAL

Degree of Purity:	98.6 %
Toxic or Hazardous Impurities:	none
Non-hazardous Impurities (> 1% by weight):	1.4 % (not characterised)
Additives/Adjuvants:	none

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as a film or paper-manufacturing chemical.

The notified chemical will not be manufactured in Australia. It will be imported in a polylined bag within a fibre carton containing 11.2 kg of the notified chemical per carton. Import volumes for the notified chemical are estimated to be 4 000 kg for the first year and is expected to rise to 40 000 kg by the year 2001.

6. OCCUPATIONAL EXPOSURE

CIN 10095204 will be imported in a polylined bag within a fibre carton. Each carton will contain 11.2 kg of CIN 10095204. The transport and storage workers are unlikely to be exposed to the notified chemical under normal circumstances.

At the mix tank site, 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 in multi-batch runs. The approximate volumes of the batches in mix tanks were not provided. The addition of the notified chemical will take approximately 5 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.

To reduce airborne concentrations, the addition of the notified chemical to the mix tank will be conducted using air extractors fitted with fiberglass air filters and mechanical ventilation. Workers handling the dry powder are to wear company provided overalls, safety glasses, disposable vinyl gloves, and disposable dust and particle marks, as described in the submission.

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 closely controlled 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.

7. PUBLIC EXPOSURE

Following import, the notified chemical will be only available to industrial processors at one site in Australia, and not to the general public. In the film and paper, the notified chemical remains under overcoat layers which prevents subsequent potential for public exposure. No public exposure is anticipated from the manufacture or handling of photographic films or paper.

Public exposure from disposal and transport is expected to be negligible. In the event of an accident, the spill will be contained and the material will be collected and placed into suitable containers for disposal. It is expected that end products containing photographic film or paper treated with the notified chemical would be disposed of mostly by landfill or incineration as domestic wastes.

8. ENVIRONMENTAL EXPOSURE

Release

Release of the chemical during the film/paper manufacturing process described above is limited to the one site in Victoria. Residues in various wastes from that site could end up in sewage effluent, in secured landfill sites or in material subsequently processed for silver recovery in the USA. Once the chemical becomes part of the article, the gelatin layers containing the notified chemical in low concentrations are securely bound to the film or paper base and overcoated by protective layers. These surface layers will prevent direct exposure to the environment of the notified chemical. Additionally, the chemical is expected to remain immobile during the processing of the film or paper.

The notifier estimates that less than 5% of the aqueous gelatin dispersion (which contains approximately less than 15% notified chemical) from the mix tank could be released to the industrial sewer. The notified chemical is released as an aqueous dispersion to the sewer.

However, the notifier claims that any of the chemicals released from the melt tank would be trapped during the silver recovery process as “filter cake” for later silver recovery. Any chemical trapped during this process should be destroyed when the filter cake is smelted to regenerate silver. This process is performed in the USA. Additionally, the notifier estimates that up to 1% of gelatin dispersion waste may be sent to a secured landfill. Total release by this means at maximum import rates is approximately 400 kg per annum

Fate

Waste from the production of a batch of the aqueous solution is expected to be released to sewer, with secondary to tertiary sewage treatment by the Werribee treatment works. Level 1 Mackay calculations for the chemical indicate that at equilibrium approximately 84%, 7%, 7% and 2% will be partitioned to soil, sediment, water and air, respectively. This result, along with the chemical’s high partition coefficient, indicates that the notified chemical should strongly partition to the soils and sediment of Werribee treatment works.

Waste trapped in filter cake and washings from the mixing kettles are processed in the USA. Empty plastic bags used to ship the chemical will be confined to secure landfill. The cardboard boxes will be crushed and recycled. Used or waste photographic film and paper would be incinerated, or buried in landfill.

The notified chemical was found to be not readily biodegradable in the OECD 301B Test for Ready Biodegradability "CO_2 Evolution/Modified Sturm Test" (Beglinger J.M. and Ruffing C.J., 1992a). A 28-day test for ready biodegradability using unacclimated micro-organisms as the inoculum showed 14% degradation at 10 $mg.L^{-1}$, based on carbon dioxide evolution. However, due to the stringency of the test, low CO_2 evolution does not necessarily mean that the test substance is not degradable under environmental conditions, or after wastewater treatment. The chemical's inherent biodegradability was not measured.

The high partition coefficient, moderate molecular weight and very low water solubility of the notified chemical would indicate a potential for bioaccumulation (Connell DW, 1989). However, any potential for bioaccumulation would be moderated by limited exposure to natural waters

9. EVALUATION OF TOXICOLOGICAL DATA

Acute Toxicity

Summary of the acute toxicity of CIN 10095204

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	> 2 000 $mg.kg^{-1}$	(Shepard KP, 1991d)
acute dermal toxicity	rat	> 2 000 $mg.kg^{-1}$	(Shepard KP, 1991b)
skin irritation	rabbit	non-irritant	(Shepard KP, 1991a)
eye irritation	rabbit	slight irritant	(Shepard KP, 1991c)
skin sensitisation	guinea pig	non-sensitiser	(Shepard KP, 1991e)

9.1.1 Oral Toxicity (Shepard KP, 1991d)

Species/strain:	rat/CD(SD)BR VAF/Plus
Number/sex of animals:	5/sex
Observation period:	14 days
Dose:	2 000 $mg.kg^{-1}$

Method of administration:	20% suspension of the test material in 0.5% aqueous suspension of guar gum, administered by gavage
Clinical observations:	reduced amount of faeces in all animals on the day following dosing; no other abnormal signs were observed at any time during the study
Mortality:	nil
Morphological findings:	none
Test method:	according to OECD Test Guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
LD_{50}:	> 2 000 $mg.kg^{-1}$
Result:	the notified chemical was of low oral toxicity in a limit study in rats

9.1.2 Dermal Toxicity (Shepard KP, 1991b)

Species/strain:	rat/CD(SD)BR VAF/PlusT
Number/sex of animals:	5/sex
Observation period:	14 days
Dose:	2 000 $mg.kg^{-1}$
Method of administration:	neat test substance administered as a solid moistened with water, under an occlusive wrap for 24 hours

Clinical observations:	discolouration of the hair at the application site was noted for all animals immediately after termination of exposure one female had signs of dehydration on day 7
Mortality:	nil
Morphological findings:	none; tissues were not collected for histopathological examination
Test method:	according to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
LD_{50}:	> 2 000 $mg.kg^{-1}$
Result:	the notified chemical was of low dermal toxicity in a limit study in rats

9.1.3 Inhalation Toxicity – not conducted

9.1.4 Skin Irritation (Shepard KP, 1991a)

Species/strain:	rabbit/Hra:(NZW)SPF
Number/sex of animals:	3/unspecified
Observation period:	14 days
Method of administration:	dose of 0.5 g of test material administered as a solid moistened with water, to the shaved dorsal skin and held in place by an occlusive wrap for 4 hours
Test method:	according to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the notified chemical was not irritating to the skin of rabbits

9.1.5 Eye Irritation (Shepard KP, 1991c)

Species/strain:	rabbit/Hra(NZW)SPF
Number/sex of animals:	6/unspecified
Observation period:	3 days
Method of administration:	dose of 0.1 g of test material was instilled into the conjunctival sac of one eye of each animal; in three animals the eyes were irrigated
Unirrigated eyes:	signs of irritation included slight to moderate erythema and slight oedema of the conjunctiva and nictitating membranes, slight erythema of the lids; slight discharges were also observed in two animals; these signs had regressed in one animal by 48 hours; signs of irritation in the remaining animals persisted for 72 hours and had regressed at day 7 of examination no corneal or adnexal staining was observed when tested with fluorescein dye
Irrigated eyes:	immediate irrigation had a palliative effect; signs of irritation were limited to slight erythema of the conjunctiva and nictitating membranes one hour after dosing; these signs had regressed by 24 hours; no discharges were observed at any time during the study no corneal or adnexal staining was observed when tested with fluorescein dye
Test method:	according to OECD test guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the notified chemical was slightly irritating to the eyes of rabbits

9.1.6 Skin Sensitisation by Buehler method (Shepard KP, 1991e)

Species/strain:	guinea pig/Crl (HA)BR VAF/PlusT
Number of animals:	20: 10 tests and 10 controls (5/sex/group)
Induction procedure:	Test animals: Day 0: a dose of 0.5 g of neat test material

was applied to a fibre pad of approximately one inch square in size moistened with water; the fibre pad containing the test material was applied to the backs of 10 guinea pigs and held in place by an occlusive dressing for 6 hours; test sites were wiped free of excess test material and observations were made at 24 and 48 hours after application

Days 7 and 14: a similar dose as on day 0 was applied to the same test area

Challenge procedure:

Day 28: Test animals:
neat test material was applied by occlusive dressing for 6 hours to the backs of 10 test animals on the opposite side of the midline from the side used for induction; test sites were wiped free of excess test material and observations were made at 24 and 48 hours after application
Control animals:
10 control animals were subjected to the same challenge to differentiate between dermal irritation and sensitisation

Challenge outcome:

Challenge concentration	***Test animals***		***Control animals***	
	24 hours*	***48 hours****	***24 hours***	***48 hours***
100%	**0/10	0/10	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Test method: according to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)

Result: the notified chemical was not a skin sensitiser to guinea pigs

9.2 Repeated Dose Toxicity (David RM, 1992)

Species/strain: rat/Sprague-Dawley (CD®(SD)BR/VAF Plus)

Number/sex of animals: 5/sex

Method of administration:	gavage
Dose/Study duration:	Test: 0, 100, 300 or 1 000 mg.kg^{-1}, 5 days per week for 30 days Control: vehicle (corn oil) only Low dose: 100 mg.kg^{-1} Mid dose: 300 mg.kg^{-1} High dose: 1 000 mg.kg^{-1}
Clinical observations:	no deaths were observed; one male from the high dose group was euthanised because of trauma no compound-related signs of toxicity were observed; other observations include: nasal discharge or decreased amount of faeces which were observed occasionally; sialorrhea (excessive salivation) was observed in 4/10 high-dose group immediately following dosing no significant differences in body weight were observed; feed consumption by both sexes in high-dose group and females in mid-dose group was statistically lower than the control group on Day 4 but not at any other time of the study
Haematology	in male rats, prothrombin times in mid- and high-dose groups were significantly increased by 43% and 70%, respectively, compared with control groups; in females, erythrocyte counts, haemoglobin concentrations and haematocrit were significantly lower in treated animals; although the changes were within the normal limits, the effects were dose-related and considered to be toxicologically significant higher incidence of abnormal red cell morphology was also observed in all treated groups statistically lower percentages of monocytes in all treated groups were observed, compared with controls; percentages of lymphocytes and eosinophils were statistically higher in high- and mid-dose groups, respectively; however, these changes in the differential leukocyte count were variable within the groups and the study authors

	did not consider them to be biologically significant
Clinical chemistry	albumin was significantly lower in low- and mid-dose male groups, compared with the control group; however, the differences were minor and the study authors did not consider them to be biologically significant
	higher mean sorbitol dehydrogenase (SDH) was observed in high-dose male groups, compared with other groups; this was due to an extremely high SDH value in one rat that under microscopic examination had diffuse fibrosis of the caudate lobe of the liver; since this lesion occurred only in one animal, the increase in SDH was not considered to be treatment-related
	alanine aminotranferase (ALT) was statistically higher in mid- and high-dose female groups while creatinine in all treated groups was statistically lower than in the control group; however, the study authors did not consider the changes in creatinine to be biologically significant
Organ Weights:	significantly higher mean absolute and relative (to body weight) liver weights were observed in all treated groups, with the exception of relative liver weights in low dose males; relative liver weights in both sexes and absolute weights in females were increased in a dose-dependent manner
	increased mean relative (to body weight) thymic weight of low-dose females was observed but this not considered to be biologically meaningful since similar findings were not observed at higher doses

Histopathology:	treatment-related hypertrophy of hepatocytes in both sexes was observed; however, in the absence of degenerative changes, this was considered as an adoptive response rather than a sign of toxicity other incidental findings included: accessory liver lobe fibrosis, cytoplasmic vacuolation of the hepatocytes, and haemorrhage, oedema, and acute inflammation of the lungs; these changes were not considered treatment-related since the presence of an accessory liver lobe is a common developmental variation and microscopic changes were secondary to torsion; hepatocyte cytoplasmic vacuolation was also frequently seen in control groups; haemorrhage, oedema an acute inflammation were observed only in one high-dose animal
Test method:	similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	increased liver weight (seen at all doses) and increased ALT activity, and hypertrophy of the liver (seen at higher doses) suggest that the liver may be a target organ; increased prothrombin time was observed in males at higher doses; lower erythrocyte counts, haemoglobin concentrations and haematocrit were noted in females at all tested doses; higher incidence of abnormal red cell morphology was also observed in all treated groups; a no-observed-effect-level (NOEL) could not be determined

9.3 Genotoxicity

***Salmonella typhimurium* Reverse Mutation Assay (Lawlor TE, 1992)**

9.3.1

Strains:	*S. typhymurium* TA98, TA100, TA1535, TA1537, TA 1538
Concentration range:	333, 667, 1 000, 3 300, 6 670, 10 000 μg.plate^{-1}
Test method:	according to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the notified chemical did not cause an increase in the number of revertants per plate in any of the bacterial strains tested in the presence and absence of microsomal enzyme from induced-rat liver S9

9.3.2 Chromosome Aberration Assay in Chinese Hamster Ovary (CHO) Cells (Barber ED, 1992)

Species/strain:	CHO
Dose range:	with metabolic activation: 2.5 – 80 μg.mL^{-1} in 10 and 20 hours without metabolic activation: 2.5 – 10 μg.mL^{-1} in 10 hours 7.5 – 20 μg.mL^{-1} in 20 hours
Test method:	according to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the notified chemical did not induce chromosomal aberrations in CHO cells in the presence or absence of metabolic activation

9.4 Overall Assessment of Toxicological Data

CIN 10095204 shows low acute oral and dermal toxicity in rats with LD_{50} values greater than 2 000 mg.kg^{-1} for both administration routes. CIN 10096270 is not irritant to rabbit skin; however, it caused slight irritation to the rabbit eye. CIN was not considered to be a dermal sensitiser in guinea pigs.

In a repeat-dose oral toxicity study, increased ALT activity, liver weight and hypertrophy of the liver suggests that the liver may be a target organ. Increased prothrombin time was observed in males at higher doses. Lower erythrocyte counts, haemoglobin concentrations and haematocrit were noted in females at all tested doses. Although the changes were within the normal limits, the effects were dose-related and therefore considered being toxicologically significant. In all treated groups, higher incidence of abnormal red cell morphology was also observed. A NOEL could not be determined.

CIN 10095204 was not mutagenic in *Salmonella typhimurium* strains with or without metabolic activation. Similarly, the notified chemical did not induce chromosomal aberrations in CHO cells *in vitro* in the presence and absence of metabolic activation.

Based on the animal studies summarised above, CIN 10095204 is unlikely to be classified hazardous according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier has supplied the following ecotoxicity studies. The tests were carried out to OECD Test Methods at facilities complying with OECD Principles of Good Laboratory Practice.

Test	Species	Results (95% confidence interval	Reference
Mean Measured concentrations			
Acute Toxicity 96 hour Static OECD TG 203	Fathead Minnow (*Pimephales promelas*)	LC_{50} > 210 $mg.L^{-1}$ (inestimable) NOEC = 210 $mg.L^{-1}$	(Forsythe SL and Hirsch MP, 1992)
Acute Immobilisation 48 hour Static OECD TG 202	Water Flea (*Daphnia magna*)	EC_{50} < 10 $\mu g.L^{-1}$ (inestimable) NOEC = 0.37 $\mu g.L^{-1}$ [a] (0-2.6 $\mu g.L^{-1}$)	(Hirsch MP, 1993)
Chronic Toxicity 21 day Flow-through OECD TG 202 [b]	Water Flea (*Daphnia magna*)	20-d EC_{50} = 9.6 $\mu g.L^{-1}$ (6.4-13 $\mu g.L^{-1}$) 14-d LOEC [c] = 6.4 $\mu g.L^{-1}$ 14-d NOEC [c] = 3.0 $\mu g.L^{-1}$	(Putt AE, 1995)
Nominal concentrations			
Growth Inhibition 72 hour Static OECD TG 201	Green Algae (*Selenastrum capricornutum*)	EC_{50} > 10 $mg.L^{-1}$ NOEC = 10 $mg.L^{-1}$	(Hughes JS and Williams TL, 1993)
Respiration Inhibition 3 hour Direct addition OECD TG 209	Aerobic Waste Water Bacteria	EC_{50} > 1 000 $mg.L^{-1}$ NOEC = 1 000 $mg.L^{-1}$	(Beglinger JM and Ruffing CJ, 1992b)

*NOEC - no observable effect concentration

a. The concentration values were transformed using natural logarithms and the results were fit with the Probit model, using statistical software. The NOEC and associated 95% confidence limits were estimated allowing for 10% immobility.

b. Since OECD Test Guideline 201 requires only a 14 day exposure for chronic testing with daphnids, the extension to 21 days provided an exposure period consistent with the requirements of EPA TSCA Guideline # 797.1330.

c. Based on reproduction through 14 days.

Fish

The acute toxicity to Flathead Minnow was determined in a 96 hour, static, aquatic effects test. The exposure solutions were prepared by the direct addition of appropriate amounts of the chemical to the test vessels. Exposure concentrations were the analysed mean values of the test concentrations at times 0 and 96 hours, i.e. mean test concentrations measured 58%, 22.4% and 20.9% of nominal concentrations 10, 100 and 1 000 $mg.L^{-1}$ respectively.

No account was given for the losses, though the measured concentrations were clearly above the solubility limit. However, it is reported in the range finding test for the daphnia study that the test chemical formed a layer of white precipitate matter at the test vessel solution surface. This particulate matter at the surface made observations difficult.

The test chemical did not cause minnow mortality in any of the exposure concentrations during the test. No observable, adverse effects on the fish at any concentrations as noted.

Water flea

Acute

The acute toxicity of the notified chemical was determined in four 48-hour, static, aquatic effects tests. The first study was conducted as a range-finding test. The second study was considered unacceptable as there was suspected interaction of the test article with the N,N-dimethylformamide carrier solvent. The third study was unacceptable as there were problems associated with the analyses of the test solutions.

During the fourth test, the notified chemical was prepared as a stock solution in the carrier solvent acetone because of its limited solubility. Two replicates series (A & B) were prepared. Exposure concentrations used were derived from the analysed mean values of the test article stock solution (in acetone) at times 0 and 48 hours. Measured concentrations were 0.01, 0.05, 0.10, 0.87, 1.56, 2.82, 5.08 $mg.L^{-1}$ (for 0.01, 0.05, 0.10, 0.86, 1.54, 2.78 and 5.00 $mg.L^{-1}$ nominals, respectively).

No daphnids were found to be mobile at 48 hours at 0.10 $mg.L^{-1}$, with only 3 mobile at 0.05 $mg.L^{-1}$. All daphnids were determined to be immobile at 6 hours at test concentrations equal to and greater than 0.87 $mg.L^{-1}$.

The 48 hour EC_{50} values for *Daphnia magna* were calculated to be < 0.01 $mg.L^{-1}$ for replicate series A and 0.02 $mg.L^{-1}$ for replicate series B. The author claims that the toxicity of the chemical in the absence of acetone is unclear as the results may be due to the combined effects of the chemical and acetone co-solvent. However, it should be noted that only 1 daphnid was recorded as immobile at 48 hours in the carrier solvent control.

Chronic

The study was performed under continuous exposure flow-through conditions for 21 days (life cycle). Nominal concentrations of 1.3, 2.5, 5.0, 10, 20 $\mu g.L^{-1}$ were chosen for the definitive study based on results of preliminary exposures. A stock solution, prepared by dissolving the test chemical with acetone, was observed to be clear and colourless. No undissolved test material (i.e. precipitate, film on solution's surface) was observed in the diluent or exposure solutions during the chronic study. Exposure concentrations were analytically confirmed on days 0, 7 and 14, with mean measured concentrations ranging from 57 to 65% of nominal.

The number of immobilised adult daphnids and observations of abnormal behaviour were recorded at test initiation and on days 1, 2, 4, 7, 8, 10, 14, 15, 17, 20 and 21. Assessments of offspring production were determined on day 7 and three times per week through day 21. Daphnid survival and reproduction rates among the control and solvent control met both the OECD and US EPA guidelines and performance criteria. Throughout the exposure period, no young were observed to be immobilised in any concentration tested.
Evaluation of the survival and reproduction of the exposed daphnids during the period between days 14 and 21, resulted in LOECs and NOECs which were unchanged relative to the conclusion determined on day 14. Refer to the table above for these and the EC_{50} results. The author also established that a maximum acceptable toxicant concentration (MATC[1]) of the notified chemical to daphnia was less than 6.4 $\mu g.L^{-1}$, but greater than 3.0 $\mu g.L^{-1}$ (geometric mean MATC = 4.4 $\mu g.L^{-1}$).

Algae

The notified chemical was tested using the solvent N,N-dimethylformamide, with *S. capricornutum* exposed to five concentrations, 0.625, 1.25, 2.50, 5.00 and 10.0 $mg.L^{-1}$ nominal. Note that the second study in the Daphnia Acute Toxicity Study was considered unacceptable due to a suspected interaction of the test chemical and this solvent (i.e. increased immobility). However, no such concern is raised in this study. It was not possible to test concentrations greater than 10 $mg.L^{-1}$ due to restrictions on the amount of solvent permissible under the test guideline (Organisation for Economic Co-operation and Development, 1995-1996). The test substance was observed to float on the surface and adhere to the sides of the test flasks.

The test solutions were analysed for the actual concentrations at the beginning and end of the test, with measured concentrations at 0 hours 0.348, 0.587, 1.03, 1.38 and 1.71 $mg.L^{-1}$. The test substance was not detected at 72 hours. Therefore, results are based on initial nominal concentrations. Biomass was determined by cell counts at 24, 48 and 72 hours.

Effects of exposure to the notified chemical ranged from 8.1% stimulation (at 0.625 $mg.L^{-1}$) to 4.9% inhibition (at 5.00 $mg.L^{-1}$) after 72 hours. Neither sufficient inhibition nor any dose-response pattern was observed at any of the time periods, precluding calculation of the EC_{50}. Microscopic observations performed at 24, 48 and 72 hours revealed no abnormalities in cell size or shape in any test concentration or control.

[1] The MATC is defined as the concentration range encompassing the highest mean measured concentrations that had no significant ($p \leq 0.05$) effect on the test organism performance and the lowest mean measured concentration that significantly affected the exposed organisms. The MATC is usually expressed as the geometric mean of the LOEC and NOEC, and is estimated from the most sensitive of the performance criteria used, e.g. adult survival or cumulative numbers of offspring produced.

Waste Water Microorganisms

The inhibitory effect of the notified chemical on the respiration rate of aerobic wastewater micro-organisms of activated sludge was investigated in a 3-hour respiration test. The study examined the five nominal test concentrations 25, 50, 100, 500 and 1 000 $mg.L^{-1}$. Due to sparing aqueous solubility, the test substance was added directly to the test beakers and was tested as a particulate in the test medium.
The respiration rate of the activated sludge increased 8.3%, i.e. enhanced respiration, at the maximum concentration tested 1 000 $mg.L^{-1}$.

Summary of Aquatic Toxicity

Results from the above reported aquatic ecotoxicity studies indicate that the notified chemical is expected to be:

- practically non-toxic to fish up to the limit of its water solubility under acute exposure conditions;
- very highly toxic to aquatic invertebrates under acute exposure conditions;
- moderately (bordering highly) toxic to aquatic invertebrates under chronic exposure conditions (Mensink BJWG, Montforts M, Winjkhuizen-Maslankiewicz L, Tibosch H and Linders JBHJ, 1995); and
- non-toxic to algae and waste water micro-organisms of activated sludge up to the limit of its water solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

A maximum of 12 batches per day would result in less than 50 kg of the notified chemical released per day. The notified chemical is released as an aqueous dispersion to the sewer. In the sewer, this quantity will be diluted initially by flow from the Kodak plant, then by the average daily inflow to the Werribee treatment plant (500 ML). This gives an approximate concentration in sewage effluent of 42.1 ppb. Further dilution of 1:10 is expected in marine receiving waters.

The predicted environmental concentration (PEC) of 4.21 ppb, in receiving waters, indicates a Q (daphnia chronic EC_{50}) value of 0.43. This hazard quotient indicates a potential aquatic hazard. However, the notified chemical will only enter the aquatic environment when the aqueous solution containing the notified substance is discharged to the sewer. Most of the chemical is expected to be removed through the sewerage treatment process by partitioning to sediment (sludge) or soils of Werribee Farm. Considering Level 1 Mackay calculations, the concentration of the notified chemical in receiving waters from Werribee farm would be reduced to approximately 0.4 ppb (90% adsorption).

Additionally, approximately 1% of the gelatin dispersion wastes may be sent to a secured landfill. This would equate to approximately 400 kg of the chemical per annum. Residues in gelatin dispersion going to secured landfill and those in film and paper going to landfill, would presumably degrade at a slow rate, depending on conditions. The chemical is not

expected to be mobile in landfill, given its low water solubility and high partition coefficient. Residues in filter cake would be destroyed during smelting, as would residues in used containers, paper and film if incinerated.

Considering the above, the environmental hazard from the proposed use is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Based on the results of animal studies, the notified chemical shows low oral and dermal toxicity in rats. It is not irritant to rabbit skin and not a dermal sensitiser in guinea pigs. However, it is slightly irritant to rabbit eye. There is a low occupational health risk for transport and storage workers who will be handling unopened cartons containing the notified chemical.

Workers at the mix tank site are likely to be exposed to the dusts of the notified chemical through inhalation, ocular and dermal contact during weighing, addition and mixing. Inhalation exposure will be minimised by the use of air extractors fitted with fibreglass air filters and mechanical ventilation. Workers are to wear personal protective clothing (company-provided overalls, safety glasses, disposable vinyl gloves and disposable dust and particle masks) during this process. No information was provided as to whether the mixing process is closed or open. Similarly, no information was provided on the process of transferring the gelatin dispersion into bags for storage in a cold room. Considering the particle size distribution of the chemical (38-> 2 360 μm), a certain percentage of the dry powder will be present as inspirable dust. There is a NOHSC exposure for dust of 10 $mg.m^{-3}$, measured as inspirable dust (National Occupational Health and Safety Commission, 1995). Employers are responsible for ensuring that this level is not exceeded in workplace.

Workers at the melt tank site will only be exposed to the notified chemical when the gelatin dispersion, together with other substances, is added to the melt tank. Again, no information on how this process takes place was provided. The submission states that workers will wear personal protective equipment (PPE) during this process. Showers are provided for workers to use. No other control measures are mentioned. The notified chemical is present in the gelatin dispersion at a low concentration and is reduced further in the melt dispersion. The low concentrations of the notified chemical in the gelatin and melt dispersions are unlikely to cause skin and eye irritation. The final step involves the use of automated processing equipment, therefore occupational exposure is not of concern.

It is not likely that workers should suffer adverse acute effects from handling the notified chemical. Implications for repeated exposure are less certain, since a NOEL could not be determined in repeat-dose experimental studies.

Public exposure is negligible during transport, handling and use of the notified chemical under normal conditions. In the event of an accident, the spill will be contained and the material will be collected and placed into suitable containers for disposal. The clean up and disposal procedures recommended in the Material Safety Data Sheets (MSDS) will assist in minimising public exposure in the event of a spill. There will be a widespread public contact with photographic articles containing the notified chemical. However, in the photographic

film and paper, the notified chemical will remain under overcoat layers which prevent subsequent occupational and public exposure.

13. RECOMMENDATIONS

To minimise occupational exposure to CIN 10095204 the following guidelines and precautions should be observed:

- 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 3765.1 (Standards Australia, 1990);
- Impermeable gloves or mittens should conform to AS 2161 (Standards Australia, 1998);
- Enclosed or automated processes should be employed for mixing and transfer of the notified chemical;
- 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.

There is a NOHSC exposure standard for inspirable dust of 10 $mg.m^{-3}$. Employers are responsible for ensuring that this level is not exceeded in the workplace.

This notification represents the fourth introduction of a toxic chemical (in addition to NA/535, NA/544 and NA/569) which is potentially released into the sewer from the Kodak plant. While the amounts of toxic chemicals released into the sewer has been reduced somewhat over the years, further reductions are clearly warranted.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994b).

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 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

Secondary notification under Section 64 of the Act will be required if the method of use changes in such a way as to greatly increase the environmental exposure of the notified chemical, or if additional information becomes available on adverse environmental effects of the chemical.

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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.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	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