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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

CIN 10092201

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Director
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FULL PUBLIC REPORT

CIN 10092201

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Kodak Australasia Pty Ltd (ACN 004 057 621)
173 Elizabeth St
Coburg VIC 3058

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer, (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name
Other Names
CAS Number
Molecular Formula
Structural Formula
Spectral Data
Identity of Toxic or Hazardous Impurities

Details of:
Use
Operation Description
Occupational Exposure
Release to the Environment for Each Use
which would serve to disclose the product formulation.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
France - Annex VIIA, 2001
USA - Low Volume Exemption, 1997

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
CIN 10092201

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Gas chromatography, characterisation by UV/visible spectrometry, Infrared (IR) spectrometry, ^{1}H nmr spectroscopy
Remarks	Reference spectra were supplied by the notifier

3. COMPOSITION

DEGREE OF PURITY
96.1 – 97.5 %

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)

Chemical Name	Unidentified impurities		
CAS No.	none allocated	*Weight %*	0.5 - 3

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as the pure solid.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Approximately 800 kg per annum.

USE
The notified chemical will be used as a component of photographic emulsions.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Kodak Australasia Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in sealed preweighed 5 kg fibre containers with conductive linings. The notifier did not state the mode of transport.

5.2. Operation Description

The notified chemical will be incorporated into photographic emulsions in batches, many times during a year. The solid notified chemical will be dissolved in water (< 10 % w/w) in mix tanks; the aqueous solution will be sampled for analysis, then dispensed into 10 L polyethylene bottles, from which it is added to the gelatin dispersion in a melt tank at a concentration < 1 % w/w. The gelatin dispersion will be mixed and pumped to automated enclosed processing equipment where the emulsion is applied to film or paper.

The layer containing the notified chemical in the finished film or paper will be under additional layers, and no further worker exposure to the notified chemical is expected on handling the photographic media.

5.3. Release

RELEASE OF CHEMICAL AT SITE
The bags used to import the notified chemical will contain solid residue after it is added to the mixing vessel. The air filters used during the mixing process will also contain the notified chemical. The notifier estimates that the empty bags may result in the disposal to landfill of 1.3 kg of the notified chemical each year. A further 832 grams per annum will be disposed of similarly as residue

on air filters.

The notifier estimates that approximately 0.5 % of the aqueous solution could be released to the sewer. This equates to 3.11 kg per annum being released to the sewer. Notified chemical released during automated coating of articles with the gelatin dispersion would be trapped during silver recovery in the filter cake which is sent to Eastman Kodak Co, USA to be smelted for silver regeneration. This process would destroy the notified chemical trapped in the filter cake.

RELEASE OF CHEMICAL FROM USE
Most of the notified chemical imported into Australia will be incorporated onto photographic film and paper under overcoat layers. In this form the notifier expects that the chemical will not be released to the environment.

5.4. Disposal

Containers used in shipping and air filters used when mixing the chemical will be dsiposed of to a secured landfill according to commonwealth, state and local laws.

6. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa Yellow powder

MELTING POINT 170°C (decomposes)

METHOD EC Directive 92/69/EEC A.1 and A.2 Melting/Freezing Temperature; Boiling Temperature.
Remarks Differential scanning calorimetry was used following an initial visual estimation. Melting and decomposition were both seen, with the order being dependent on the test parameters. An exothermic reaction occurred at 170°C, with melting of the decomposed material by 200°C, both at atmospheric pressure and under reduced pressure.
TEST FACILITY Eastman Kodak Company, Technical Safety Laboratory (1998b)

DENSITY 1478.4 kg/m^3 at 4°C

METHOD OECD TG 109 Density of Liquids and Solids (Helium Pycnometer Method).
TEST FACILITY Eastman Kodak Company, Analytical Technology Division (2000g)

VAPOUR PRESSURE 1.6×10^{-13} kPa at 25°C

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure (Vapour Pressure Balance Method).
TEST FACILITY SafePharm Laboratories Ltd (2000)

WATER SOLUBILITY 100.6 g/L at 20°C

METHOD OECD TG 105 Water Solubility (Shake Flask Method).
Remarks Analytical Method: HPLC/UV
No co-solvent was used.
TEST FACILITY Eastman Kodak Company, Chemical Quality Services Division (1998c)

HYDROLYSIS AS A FUNCTION OF PH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

PH	*T (°C)*	$t_{½}$
4	25	95.7 hr
7	25	46.1 hr
9		

Remarks $T_{1/2}$ at 25°C for pH 9.0 was not determined because greater than 50 % (99 %) hydrolysis was observed after 2.4 hours at 50°C.
The notified chemical may be classified as slightly hydrolysing at pH 4 and 7 and very rapidly hydrolysing at pH 9.
TEST FACILITY Eastman Kodak Company, Environmental Analytical Services (2000h)

PARTITION COEFFICIENT (n-octanol/water) log Pow at 20°C = -2.06

METHOD OECD TG 107 Partition Coefficient (n-octanol/water): HPLC Method.
Remarks Analytical Method: HPLC
TEST FACILITY Eastman Kodak Company, Environmental Analytical Services (1998d)

ADSORPTION/DESORPTION – screening test log K_{oc} = not determined

METHOD OECD TG 106 Adsorption - Desorption Using a Batch Equilibrium Method.
Remarks Not determined due to the low recovery of the notified chemical because of its instability in aqueous solution (soil pH range 4.7-7.5 – 3 soils used). However, based on the water solubility and Log Pow results, adsorption to soils is expected to be relatively weak.
TEST FACILITY Eastman Kodak Company, Environmental Analytical Services (2000i)

ADSORPTION/DESORPTION – main test

Remarks Not determined due to the low recovery of the notified chemical during the screening test.

DISSOCIATION CONSTANT pKa = 5.4

METHOD OECD TG 112 Dissociation Constants in Water.
TEST FACILITY Eastman Kodak Company, Environmental Analytical Services (2000j)

PARTICLE SIZE

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions (Sonic Sifter Method).

Range (μm)	*Mass (%)*
38 - 75	7.3
75 - 150	43.0
150 - 300	17.1
300 - 850	11.2
850 2360	18.7
> 2360	2.7

Remarks Median particle size 147.1 μm
TEST FACILITY Eastman Kodak Company, Analytical Technology Division (2000k)

SURFACE TENSION 71.8 mN/m at 20°C

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
Remarks Concentration: not stated
The notified chemical is not surface active, based on the results of the determination.
TEST FACILITY Eastman Kodak Company, Environmental Analytical Services (2000l)

FLASH POINT
Remarks Not applicable for solids.

FLAMMABILITY LIMITS

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks Not highly flammable
TEST FACILITY Eastman Kodak Company, Technical Safety Laboratory (1998b)

AUTOIGNITION TEMPERATURE > 400°C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks No self-ignition was observed.
TEST FACILITY Eastman Kodak Company, Technical Safety Laboratory (1998b)

EXPLOSIVE PROPERTIES
Remarks Not explosive, based on structural features.

REACTIVITY

Remarks Expected to be stable under normal environmental conditions; structural features do not indicate the likelihood of oxidising behaviour or other high reactivity.

7. TOXICOLOGICAL INVESTIGATIONS

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 401 Acute Oral Toxicity.
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).
Species/Strain Rat/Sprague-DawleySAS:VAF(SD)
Vehicle 0.5 % carboxymethylcellulose.
Remarks - Method No protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5/sex	500	0/10
II	5/sex	1000	10/10
III	5/sex	2000	10/10

LD50 707 mg/kg bw
Signs of Toxicity All animals in Group II were found dead by 24 hours; all animals in Group III were found dead by 4 hours. Slight to severe weakness was observed prior to death. All animals including those in Group I showed bright yellow urine. Bodyweight increases were seen for the surviving animals.
Effects in Organs For animals in Groups II and III, test material was observed in the stomach, duodenum and jejunum. Minimal to moderate oedema of the gastric mucosa of the majority of the animals and minimal haemorrhage of the gastric mucosa of several Group III animals was observed. Incomplete collapse of the lungs and thymus haemorrhage were also noted in a number of animals.
Group I animals showed no gross abnormalities at necropsy.
Remarks - Results The cause of mortality was not determined. The findings in the lungs and thymus were considered likely to be agonal effects.
In a range finding test using one animal per sex at doses of 250, 500 and 1000 mg/kg bw, the animals at 1000 mg/kg bw both died on the day of

dosing, while the other animals survived the 7 day observation period.

CONCLUSION The notified chemical is harmful via the oral route.

TEST FACILITY Eastman Kodak Company, Toxicological Sciences Laboratory (1997c)

7.2. Acute toxicity - dermal

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.
EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.

Species/Strain	Rat/Sprague-DawleySAS:VAF(SD)
Vehicle	Moistened with water.
Type of dressing	Occlusive.
Remarks - Method	No protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5/sex	2000	0/10

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Brown staining of the skin and hair at the application site, persisting throughout the study.
Signs of Toxicity - Systemic	No clinical signs of systemic toxicity were observed.
Effects in Organs	No gross abnormalities were seen at necropsy.
Remarks - Results	None

CONCLUSION The notified chemical is of low toxicity via the dermal route.

TEST FACILITY Eastman Kodak Company, Toxicological Sciences Laboratory (1997d)

7.3. Irritation – skin

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/Hra:(NZW)SPF
Number of Animals	3, sex not stated
Vehicle	Moistened with water.
Observation Period	3 days
Type of Dressing	Occlusive.
Remarks - Method	No protocol deviations.

RESULTS

Remarks - Results	No erythema or oedema was observed at the application site at 1, 24, 48 or 72 hours after treatment. Light brown staining persisted throughout the study.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY Eastman Kodak Company, Toxicological Sciences Laboratory (1997e)

7.4. Irritation - eye

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain: Rabbit/Hra:(NZW)SPF
Number of Animals: 6, sex not stated
Observation Period: 3 days
Remarks - Method: The eyes of three of the animals were irrigated with distilled water immediately following instillation. Scores for these animals are not included in the table below.
An EYTEX in vitro assay performed prior to the main study indicated that the notified chemical would have at most minimal eye irritant effects.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1	0.33	0.33	2	< 72 hours	0
Conjunctiva: chemosis	0	0	0	1	< 24 hours	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results: Slight discharge (no scores provided) was seen for two animals with unwashed eyes and one animal with a washed eye at 1 hour. No chemosis was seen in the washed eyes.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: Eastman Kodak Company, Toxicological Sciences Laboratory (1997f)

7.6. Skin sensitisation

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 406 Skin Sensitisation - Maximisation Test.
EC Directive 96/54/EC B.6 Skin Sensitisation – Maximisation Test.

Species/Strain: Guinea pig/Crl:(HA)BR VAF/Plus
PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: 5 % in corn oil
topical: 25 % in petrolatum
MAIN STUDY
Number of Animals: Test Group: 20 Control Group: 10
induction phase: Induction Concentration:
intradermal injection 5 %
topical application 25 %
Signs of Irritation: No signs of irritation were seen at the injection sites. Irritation scores of up to 2 were observed in the test group 24 hr following topical induction; scores of 0 or 1 were observed for the control group. Irritation scores of 2 were observed at the induction site prior to topical induction, due to the use of sodium lauryl sulphate.
CHALLENGE PHASE: topical application: 25 %
Remarks - Method: The maximum non-irritating concentrations in the initial screen were the

highest concentrations tested.
Prior to topical induction, irritation was induced by application of sodium lauryl sulphate in petrolatum.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after Challenge*	
		24 h	*48 h*
Test Group	25 %	0/19	0/19
Control Group	25 %	0/9	0/9

Remarks - Results: Two animals, one test and one control, died during the study; the causes were not treatment related.

CONCLUSION: There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY: Eastman Kodak Company, Toxicological Sciences Laboratory (1997g)

7.7. Repeat dose toxicity

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain
Route of Administration: Oral – gavage
Exposure Information: Total exposure days: 28 days;
Dose regimen: 7 days per week.
Vehicle: Corn oil
Remarks - Method: Due to a proposed mechanism of toxicity, measurements of homocysteine concentrations were performed. A preliminary study using 3 females per dose for 14 days with a maximum dose level of 750 mg/kg bw/day was performed. The maximum dose level for the main study of 750 mg/kg bw/day was selected as no mortality was seen in the preliminary study.
No protocol variations were reported.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I	5/sex	0	0/10
II	5/sex	75	0/10
III	5/sex	225	0/10
IV	5/sex	750	0/10

Mortality and Time to Death
There were no unscheduled deaths during the study.

Clinical Observations
Orange discolouration of urine was seen in all treated animals, with minimal to minor severity in Group IV, minimal severity in Group III, and occasional minimal severity in Group II. Reduced volume and softening of faeces was seen in a number of Group IV animals in the early part of the study. Reduced food consumption and body weights were seen for Group IV, particularly males, in the first half of the study.
Neurological effects (head flick, head search, circling) were seen in Group IV animals, particularly in the males.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Homocysteine analysis showed a decrease in plasma levels for group IV males, although liver and urine levels were unchanged. No differences in haematology or clinical chemistry parameters were seen for the females. For Group IV males, mean urea nitrogen was increased compared with controls, while the mean serum thyroxine level was decreased. Mean platelet counts for all treated males were lower than controls, while mean white blood cell counts and absolute lymphocyte values for Group II and IV males were lower than controls.

Effects in Organs

No differences in organ weights were seen in the female groups. For the males in Groups III and IV, a reduction in absolute and relative thymus weight was observed. A number of gross lesions observed at necropsy were considered scattered and not likely to be treatment related; however minor focal discolouration of the lungs in one Group IV female was considered by the study authors to be possibly treatment related.

Histopathological changes in the thyroid and lungs were considered by the study authors to be potentially treatment related. Mild follicular cell hypertrophy of the thyroid was observed in all treated male groups, with increased incidence at higher doses; mild to moderate follicular cell hypertrophy was seen in all Group IV females. Among the males, no trends in lung lesions with dose were observed. Among the females, increased severity and incidence of pulmonary haemorrhage and interstitial pneumonitis was observed with increasing dose. Lung lesions in the males showed signs of being agonal in origin, but those in the females appeared to be longer standing. Other histopathological findings were considered to be scattered incidences without relationship to treatment with the notified chemical.

Remarks – Results

Haematological differences among the male rats were considered incidental, as no changes in prothrombin time were observed corresponding to differences in platelet counts, and the mean white blood cell counts and absolute lymphocyte values for the control males were at the high end of the historical range. The origin of the lung effects seen in the females was not clear. The incidence (all animals) and severity (mild to moderate) of haemorrhage seen in the Group IV females was considered to be significant, while the incidence in the lower treatment groups (2 and 1 animals in Groups II and III, respectively) did not indicate clear treatment relationship. Pneumonitis was possibly related to rat coronavirus infection.

The study authors also indicated that the serum urea nitrogen levels in the males of Group IV were not likely to be toxicologically significant in the absence of other indications of impaired kidney function, and that the thymus weight differences may be related to haemorrhages attributed to the gavage procedure.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 225 mg/kg bw/day in this study, based on clinical signs, particularly neurobehavioural effects, and thyroid effects (follicular cell hypertrophy in the Group IV females and changes in thyroid function marker in Group IV males).

TEST FACILITY	Eastman Kodak Company, Toxicological Sciences Laboratory (2000m)

7.8. Genotoxicity - bacteria

TEST SUBSTANCE	Notified chemical.
METHOD	EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2 uvrA (pKM101).
Metabolic Activation System	10 % rat liver S9 fraction from animals pretreated with Aroclor 1254
Concentration Range in Main Test	a) With metabolic activation: 10 - 3330 µg/plate. b) Without metabolic activation: 10 - 5000 µg/plate (*S. typhimurium*) c) With metabolic activation: 33.3 - 5000 µg/plate. d) Without metabolic activation: 33.3 - 5000 µg/plate (*E. coli*).
Vehicle	Water
Remarks - Method	Three independent tests were carried out in triplicate.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	3330	-	-	1000
Test 2		-	-	1000
Test 3		-	-	1000
Absent				
Test 1	3330	1000	-	1000
Test 2		2000	-	333
Test 2		3330	-	333

Remarks - Results: Increases in revertant colonies were observed only for *S. typhimurium* TA 100, both in the presence and absence of metabolic activation. No increases were observed for the other strains tested. The increases for TA 100 in the presence of metabolic activation were up to 2.1-fold, 1.8-fold and 1.8-fold in the three experiments; in the absence of metabolic activation, the increases were up to 1.9-fold, 2.0-fold and 2.2-fold.
Appropriate positive controls were used and resulted in large increases in the numbers of revertant colonies in all cases, confirming the sensitivity of the test system.

CONCLUSION: The notified chemical was mutagenic to bacteria under the conditions of the test.

TEST FACILITY: Covance Laboratories, Inc (2000a)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line: Chinese hamster ovary (CHO)
Metabolic Activation System: 1.5 % rat liver S9 fraction from animals pretreated with Aroclor 1254
Vehicle: Water
Remarks - Method: No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Present			
Test 1	15.0, 21.5, 30.7, 43.8, 62.5, 89.0, 127, 182, 260, 371, 530*, 755*, 1080*, 1540*, 2200	3 hr	20.1 hr
Test 2	530, 755*, 1080*, 1540*, 2200*	3 hr	20 hr
Absent			
Test 1	15.0, 21.5, 30.7, 43.8, 62.5, 89.0, 127*, 182*, 260*, 371*, 530, 755, 1080, 1540, 2200	3 hr	20.1 hr
Test 2	30.5*, 61.0*, 122*, 183*, 203, 223, 243, 263	17.8 hr	20 hr

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity	*Precipitation*	*Genotoxic Effect*
Present			
Test 1	1540	-	1080
Test 2	2200	-	2200
Absent			
Test 1	260	-	371
Test 2	183	-	183

Remarks - Results: Increases in the numbers of cells containing chromosomal aberrations were seen in all tests, both in the presence and absence of metabolic activation.
Appropriate positive controls were used and resulted in large increases in the numbers of cells containing chromosomal aberrations in all cases, confirming the sensitivity of the test system.

CONCLUSION: The notified chemical was clastogenic to CHO cells treated in vitro under the conditions of the test.

TEST FACILITY: Covance Laboratories, Inc (2000b)

7.10. Genotoxicity – in vivo

TEST SUBSTANCE: Notified chemical.

METHOD: Based on OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain: Mouse/Crl:CD-1(ICR)BR
Route of Administration: Oral – gavage.
Vehicle: Water
Remarks - Method: The test used an in-house protocol stated to be based on the OECD guideline. Two doses, 24 hr apart, were given to the test animals. Sacrifice was 24 hr after the last dose.

Group	*Number and Sex of Animals*		*Dose mg/kg bw*	*Sacrifice Time hours*
	I	6 male	0	48
	II	6 male	200	48
	III	6 male	400	48
	IV	12 male	800	48
	V	6 male	8 (CP)	48

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity: In a preliminary test, 1/3 males died after a second dose at 800 mg/kg bw, while 2/3 animals of each sex died after a single dose at 1000 and 1200 mg/kg bw; all animals died after a single dose at 2000 mg/kg bw. In the main test, 1/12 of the animals at 800 mg/kg bw died after the second dose.
No significant change in the polychromatic erythrocyte (PCE)/normal chromatic erythrocyte (NCE) ratio was observed, indicating that the notified chemical was not cytotoxic to bone marrow.

Genotoxic Effects: No significant increase in the proportion of micronucleated PCEs was observed following treatment with the notified chemical.

Remarks - Results: The positive control (CP) resulted in a significant increase in micronucleated PCEs, confirming the sensitivity of the test system.

CONCLUSION: The notified chemical was not clastogenic in this in vivo mouse

micronucleus test under the conditions of the test.

TEST FACILITY Covance Laboratories, Inc (2000c)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum Activated sludge sample
Exposure Period 20 days
Remarks - Method The notifier indicated that the test was not extended beyond day 20 as it was apparent that 60 % degradation of the chemical would not be reached by day 28.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% degradation*	*Day*	*% degradation*
20	5, 13	28	82

Remarks - Results The test substance attained a maximum of 13 % degradation after 20 days and therefore could not be considered readily biodegradable under OECD guidelines requiring > 60 % degradation by day 28. The standard material attained 82 % degradation indicating the viability of the culture and test conditions.

CONCLUSION The notified chemical is not readily biodegradable.

TEST FACILITY Eastman Kodak Company, Environmental Sciences Section (1998e)

8.1.2. Biochemical/chemical oxygen demand (BOD/COD)

TEST SUBSTANCE Notified chemical

RESULTS

BOD (5 days) g/g	*COD g/g*	*BOD/COD*
0.12	1.61	0.07

CONCLUSION The notified chemical is not readily biodegradable.

TEST FACILITY Eastman Kodak Company, Environmental Sciences Section (2000n-o)

8.1.3 Bioaccumulation

No bioaccumulation data were provided in the notification dossier. The low molecular weight indicates that the notified chemical has the potential to bioaccumulate. However, bioaccumulation is not expected to occur due to the high water solubility and instability of the notified chemical in the aquatic environment.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE — Notified chemical.

METHOD
- Species: *Pimephales promelas*
- Exposure Period: 96 hours
- Water Hardness: 120 mg $CaCO_3$/L
- Analytical Monitoring: HPLC with diode-array detection (DAD)
- Remarks – Method: The half-life of the notified chemical in the dilution water (pH range 8.0-8.6) was determined to be 30.4 hours. Therefore the test substance and control solutions were renewed every 24 hours.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*1h*	*24h*	*48h*	*72h*	*96h*
0		14		0	0	0	0
6.25	3.3	14		0	0	0	0
12.5	8.2	14		2	2	2	2
25	19.0	14		5	5	5	5
50	41.8	14		13	13	13	13
100	88.1	14		12	12	14	14

- LC50: 19.6 mg/L at 96 hours.
- NOEC (or LOEC): 3.3 mg/L at 96 hours.
- Remarks – Results: Actual concentrations of the notified chemical in the test solutions were used to calculate LC50 and NOEC. The LC50 values and 95 % confidence intervals were calculated using the Spearman-Karber method. The highest analysed concentration causing no mortality was 3.3 mg/L. The lowest analysed concentration causing 100% mortality was 88.1 mg/L. Sublethal effects were only observed after 24 hours at the highest concentration tested. Sublethal responses were depressed activity compared to controls and fish positioned at the surface.

CONCLUSION — The 96 hour LC50 value indicates that the notified chemical would be classified as slightly toxic to fish (Mensink *et al.* 1995).

TEST FACILITY — Eastman Kodak Company, Environmental Sciences Section (2000p)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE — Notified chemical.

METHOD
- Species: *Daphnia magna*
- Exposure Period: 48 hours
- Water Hardness: 120 mg $CaCO_3$/L
- Analytical Monitoring: HPLC/DAD
- Remarks - Method: The half-life of the notified chemical in the dilution water (pH range 8.0-8.7) was determined to be 30.4 hours. Therefore, the test substance and control solutions were renewed every 24 hours.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	0	20	0	0
6.25	2.0	20	1	1
12.5	6.6	20	0	0
25	17.0	20	0	1
50	37.6	20	0	1
100	80.6	20	4	5

LC50	> 80.6 mg/L at 48 hours
NOEC (or LOEC)	37.6 mg/L at 48 hours
Remarks - Results	Actual concentrations of the notified chemical in the test solutions were used to calculate EC50. The statistical method used to determine the EC50 values was Spearman-Karber. The highest concentration causing no significant immobility within the test period was 37.6 mg/L.
CONCLUSION	The 48 hour EC50 value indicates that the notified chemical would be classified as slightly toxic to daphnids (Mensink *et al*. 1995).
TEST FACILITY	Eastman Kodak Company, Environmental Sciences Section (2000q)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Pseudokirchineriella subcapitata*
Exposure Period	72 hours
Concentration Range Nominal	0-100 mg/L
Concentration Range Actual	0-110 mg/L
Analytical Monitoring	HPLC-UV

RESULTS

Biomass		*Growth*	
Ebc50 mg/L at 72 h	*No-observed-effect conc. mg/L*	*Eg50 mg/L at 72 h*	*No-observed-effect conc mg/L*
32	7.1	79	7.1

Remarks - Results	At 72 hours the actual concentration of the notified chemical in the 0.41-6.4 mg/L (nominal) test solutions (pH range 7.8-8.7) were below quantifiable levels. The actual concentrations measured in the test solutions at 0 hours were used to calculate LC50 and NOEC. The actual values are probably lower than reported. It was reported that the algae did not impact on the actual concentration of the notified chemical in the test solutions. The difference between the measured concentrations and nominal concentrations of the notified chemical may have arisen through hydrolytic degradation.
CONCLUSION	Based on the reported EC50 values for algal growth and biomass, the notified chemical may be classified as slightly toxic to algae (Mensink *et al*. 1995). However, as noted, these values are likely to be lower than reported.

TEST FACILITY	Springborn Laboratories Inc (2000)

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge from a domestic waste water treatment plant.
Exposure Period	3 hours
Concentration Range Nominal	0-1000 mg/L
RESULTS	
IC50	316 mg/L
NOEC	50 mg/L
Remarks – Results	The EC50 value for the positive control, 3,5-dichlorophenol, was 15.8 mg/L.
CONCLUSION	The notified chemical may be classified as practically non-toxic to secondary waste water treatment micro-organisms (Mensink *et al*. 1995).
TEST FACILITY	Eastman Kodak Company, Environmental Sciences Section (2000r)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

There will be a small release of the notified chemical during the manufacture of an emulsion for photographic film and paper. The majority of the chemical will be applied to photographic film and paper in the gelatin dispersion under overcoat layers and be immobilised. These articles would consequently be dispersed widely in Australia through their use in photographic processing. Some release of the chemical could occur during processing due its ready solubility in water (EC, 1996).

The small release to the sewer during manufacturing of the photographic emulsion will equate to 3.11 kg per annum. This release will be to a municipal sewage treatment plant, Werribee, which has an average daily inflow of 500 megalitres. The total release will be spread over 100 days per annum. Thus, the predicted environmental concentration (PEC) for water is 0.06 µg/L.

The notifier has provided information on the biotic and abiotic degradability of the notified chemical. The notified chemical is not readily biodegradable according to a test carried out following OECD guidelines, but is degradable through the abiotic process of hydrolysis according to a test carried out following OECD TG 111. The half-life of the notified chemical at pH 7 was found to be 46.1 hours, and is much shorter at alkaline pH.

Based on the Log Kow of -2.06, the notified chemical waste released to the sewer will not adsorb to sludge but partition into the water compartment and be released to the aquatic environment. In the aquatic environment the notified chemical is not expected to persist given that it will be rapidly degraded through abiotic processes, particularly hydrolysis.

Notified chemical released to secured landfill as residue on empty import bags and used air filters may leach into the water compartment due to its high solubility and low n-octanol/ water partition coefficient. It will not persist in this environment due to its hydrolysable nature.

Discarded photographs and film will be disposed of to landfill where the notified chemical is

likely to be slowly released as the photographic film or paper and the emulsion coating are degraded. It is expected that the released chemical will partition to the water compartment where it will be degraded through abiotic processes, chiefly hydrolysis.

There is limited potential for bioaccumulation due to the low release of the notified chemical and because it is not expected to persist in the water compartment of the aquatic environment but degrade through abiotic processes including hydrolysis.

9.1.2. Environment – effects assessment

The ecotoxicological data provided in the dossier indicate the notified chemical is slightly toxic to aquatic organisms at all three trophic levels tested under laboratory conditions. The most sensitive species was *Pimephales promelas* with a reported LC50 at 96 hours of 19.6 mg/L. Based on a worst case assessment safety factor of 100, the LC50 for *P. promelas*, yields a PNEC for water of 196 μg/L.

The algal growth inhibition test used concentrations of the notified chemical measured at 0 hours to calculate the LC50 and NOEC values reported. This would have resulted in an under-estimation of these values due to the instability of the notified chemical in aqueous solution. After 96 hours of exposure there was greater than 20 % variation between the nominal and measured concentrations of the notified chemical in the test solutions. However, hydrolysis of the notified chemical in the aquatic environment should reduce the hazard to aquatic organisms.

9.1.3. Environment – risk characterisation

The notified chemical is not expected to pose a significant risk to the environment when used in the manner proposed. The majority of the notified chemical will be incorporated into a gelatin dispersion and coated onto photographic articles where it will be immobilised beneath overcoat layers.

There will be a low release to the sewer resulting in a PEC of 0.06 μg/L. This PEC is several orders of magnitude lower than the PNEC for the notified chemical. Given the low ratio of PEC/PNEC of 3.06 x 10^{-4}, the notified chemical is not expected to pose a significant hazard to the aquatic environment.

9.2. Human health

9.2.1. Occupational health and safety

9.2.1.1 OCCUPATIONAL EXPOSURE ASSESSMENT

Transport and Storage

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. No details of occupational exposure were provided by the notifier.

Formulation

The appropriate amount of the notified chemical, in powdered form, will be weighed from the imported bags to mix tanks to form aqueous solutions (< 10 % notified chemical) in a batch manner, many times per year. Addition to the mix tanks will be performed manually. Weighing the notified chemical will take approximately 30 minutes per batch, and addition a further 5 minutes per batch. A sample of the solution will be taken for laboratory testing. Inhalation and eye exposure to the powdered form of the notified chemical may occur because adding to the mix tank is an open process. Dermal contact with the powdered substance or the solution is also possible.

Addition of the notified chemical 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 or nitrile gloves, and a mask with particle filter.

The notifier indicates that 15 operators will be involved in producing the aqueous solutions.

The aqueous solution will be transported to the coating area in tanks. The solution will then be transferred to automated processing equipment, where the notified chemical will be incorporated into photographic films and paper. No details of the manner of transfer of the aqueous solutions from the mix tank to transfer tanks, and then to the automated system, were provided by the notifier. It is probable that dermal exposure could occur during these processes. Intermittent dermal exposure to the notified chemical is also possible during cleaning of automated processing equipment. Workers handling solutions or gelatin dispersions will use personal protective equipment comprising disposable vinyl gloves, overalls and safety glasses.

The notifier indicates that 18 operators and 4 technicians will be involved in handling the aqueous solutions.

End Use
The notifier indicates that the notified chemical will be under overcoat layers in the finished articles. Therefore no exposure of end users who handle the film or paper, such as photographers, is likely.

9.2.2. Public health

The public may be exposed to the notified chemical in its powder form following transport accidents *en-route* from the point of importation to the notifiers site. In the unlikely event of an accident, the fibre containers in which the notified chemical is imported and transported are unlikely to break. In spills that do occur, the windborne dispersal of any escaping powder may cause the lodgement of the notified chemical powder onto the skin or into the mouth, nose and eyes of nearby persons. This contact is likely to be minimal and of a transient nature. The powder particles are large and are not likely to reach the lungs. Spills will be cleaned up mechanically and disposed of as landfill.

Data on the fate of the notified chemical following development of the film or paper at various sites throughout Australia was not supplied. Release of the notified chemical from the film manufacturing site of the notifier is minimal and of low volume for the notified limited use. Small amounts of waste aqueous solution of notified chemical will be disposed of in sewage. Used film or paper containing the notified chemical and no longer required by the owner is most likely to be sent as landfill. Members of the public are thus unlikely to contact the notified chemical as an environmental contaminant.

In the course of consumer use of the end products, the notified chemical is an integral part of the emulsion layers on film or paper which in turn is itself covered by other layers. The notified chemical will not generally be accessible to human contact. The potential for exposure of the public to the notified chemical is therefore minimal.

9.2.3. Human health - effects assessment

9.2.3.1 SUMMARY OF TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 = 707 mg/kg bw	harmful
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rat, acute inhalation	test not conducted
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test.	no evidence of sensitisation.
Rat, Oral Repeat Dose Toxicity - 28 Days.	NOAEL = 225 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	mutagenic
Genotoxicity – in vitro Chromosome Aberration Assay	genotoxic
Genotoxicity – in vivo Mouse Micronucleus Test	non genotoxic

9.2.3.2 DISCUSSION

The notified chemical was found to be harmful by oral administration to rats, with 100 % mortality at 1000 mg/kg bw, although no mortality was seen at 500 mg/kg bw. Similar results were seen in the toxicity prescreen for the mouse micronucleus study, with low mortality at 800 mg/kg bw, but high mortality at 1000 mg/kg bw. No mortality was seen in rats in a repeat dose study at 750 mg/kg bw/day. In rats, the LD50 was calculated as 707 mg/kg bw. The notified chemical was found to be of low toxicity in rats by dermal application.

The notified chemical was found to be non-irritant and non-sensitising to skin, and a slight irritant to rabbit eyes, with low levels of conjunctival redness persisting beyond 48 hours.

In a 28-day repeat dose oral study in rats, a NOAEL of 225 mg/kg bw/day was established. At 750 mg/kg bw/day, neurobehavioural effects and effects on the thyroid were observed. Minor effects such as urine discolouration were observed at all doses tested.

The notified chemical was found to be mutagenic in *S. typhimurium* TA100 both in the presence and absence of metabolic activation, although no genotoxic effects were observed for the other strains tested in the bacterial mutagenicity assay. In a chromosome aberration study in vitro, clear increases in the number of cells with chromosome aberrations were induced by the notified chemical both in the presence and absence of metabolic activation. In an in vivo mouse erythrocyte micronucleus test, the notified chemical was not clastogenic.

The notifier stated that the notified chemical has not been observed to result in human health effects during use elsewhere in the world.

Based on the results of the toxicity testing using the notified chemical, it should be classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) and should carry the risk phrase R22: Harmful if swallowed. While the in vitro genotoxicity tests were indicative of potential for genotoxicity, the notified chemical would not be classified in accordance with the Approved Criteria for mutagenic effects based on the data provided. The safety phrases S24: Avoid contact with skin; and S37: Wear suitable gloves should however be applied.

9.2.4. Human health – risk characterisation

9.2.4.1 OCCUPATIONAL HEALTH AND SAFETY

Based on the results from the genotoxicity studies on the notified chemical, a precautionary approach of avoidance of exposure to the notified chemical should be used at all times. Occupational exposure to the notified chemical is most likely during film manufacture, which involves weighing out the dry powder and manually adding this to mix tanks, sampling for testing, then transferring the resultant solution, containing < 10 % notified chemical, to coating equipment. Dermal, inhalation and ocular exposure to the powder and dermal exposure to the solution are possible during these processes. Dermal exposure to the gelatin dispersion containing < 1 % notified chemical may also occur.

The risk of inhalation exposure is reduced as there is no significant proportion of the powder in the respirable size range, and as weighing and addition of the powder will be carried out under local exhaust ventilation. In addition, workers handling the dry powder are to wear company provided overalls, safety glasses, disposable vinyl or nitrile gloves, and a mask with particle filter. Workers handling solutions or gelatin dispersions will use personal protective equipment comprising disposable vinyl gloves, overalls and safety glasses.

There is little risk to occupational health and safety following incorporation into photographic film or paper, as the amount of notified chemical will be very small, and the layer containing the chemical will lie under several overcoat layers.

9.2.4.2 PUBLIC HEALTH

Public exposure to the notified chemical is expected to be limited to unlikely transport accidents involving damage to the packaging of the imported powder form. In the unlikely

event of the powder becoming windborne the large particle size of the powder will prevent the breathing in of the powder and contact with the lungs is unlikely. However the powder may contact the skin, mouth, nose and eyes. This contact is likely to be minimal and transient. A slight irritation of the eyes is possible. In the end-use products the notified chemical is present as an integral part of a photographic emulsion layer which in turn is covered by other layers. The low likelihood of exposure to the notified chemical suggest that it will not pose a significant hazard to public health when used in the proposed manner.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Environment

On the basis of the PEC/PNEC ratio:

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.2. Health hazard

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). The classification and labelling details are: R22: Harmful if swallowed.

10.3. Human health

10.3.1. Human health – Occupational health and safety

There is Moderate Concern to occupational health and safety under the conditions of the occupational settings described, based on the use of a possibly genotoxic material in open systems.

10.3.2. Human health – public

There is No Significant Concern to public health when used as specified in the notification..

11. RECOMMENDATIONS

REGULATORY CONTROLS

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R22: Harmful if swallowed
  - S24: Avoid contact with skin
  - S37: Wear suitable gloves.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical in powder solution form:
  - Local exhaust ventilation.

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical in powder solution form:
  - Enclosed equipment should be used where possible.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in powder form:
  - gloves, overalls, safety glasses, and respiratory protection.

- Employers should ensure that the following personal protective equipment is used by

workers to minimise occupational exposure to the notified chemical in solution or dispersion form:
– gloves, overalls, safety glasses.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

11.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:
– if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

12. 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.

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