File No STD/1101

30 June 2004

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

218DO

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Kodak Australasia Pty Ltd (ACN 004 057 621, ABN 49 004 057 621)
173 Elizabeth St
Coburg, Victoria 3058

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical identity
Specific use
Details of process.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Acute inhalation toxicity
Induction of germ cell damage

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LVC Permit No. 601 (2004).

NOTIFICATION IN OTHER COUNTRIES
EU (1993, 2004))

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
218DO, CIN 10084241

SPECTRAL DATA

ANALYTICAL METHOD	IR, UV-visible, ^{1}H NMR.
Remarks	Reference spectra were provided.
TEST FACILITY	Eastman Kodak (2003a, 2003b, 2003c)

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	HPLC / UV, GC/FID.
TEST FACILITY	Eastman Kodak (2003d)

3. COMPOSITION

DEGREE OF PURITY
96.5% (range 95 to 98%)

HAZARDOUS IMPURITIES
None are present at above the relevant cut-offs for classification of the notified chemical as a hazardous substance.

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported in 5 kg plastic bags in cardboard outers.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	16	16	16	16	16

USE
Component of photographic paper.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The notified chemical will be imported by sea in cardboard outer boxes, each containing several 5 kg plastic bags sealed at the neck with ties, and transported to the notifier's warehouse.

5.2. Operation description
The notified chemical will be stored at the notifier's warehouse before use. Whole bags of the notified chemical will be incorporated into water-based dispersions in a batch process involving a number of formulation steps, with a final batch size approximately 1000 L. Several batches of the dispersion may be produced per day and will be stored before use, and then used on-site as part of the coating of photographic paper. In the paper coating process, the dispersions will be pumped to automatic processing equipment. Once incorporated into the paper coating, the notified chemical will be covered by other layers and become part of the article.

5.3. Occupational exposure
Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Operators in formulation area	10	8 hours/day	250 days/year
Laboratory workers	3	1 hour/day	250 days/year
Maintenance workers	1	½ hour/week	50 weeks/year
Operators in application of coatings	<10	intermittent	infrequent

EXPOSURE DETAILS
Transport and storage
Transport and storage workers, including waterside workers, transport drivers and warehouse workers will handle sealed cardboard containers containing inner packages of the notified chemical. Warehouse workers may also handle the inner packages (sealed plastic bags). No exposure is expected except in the case of an accident that breaches the packaging.

Formulation of dispersions
Workers will undo the plastic ties on plastic bags of the notified chemical, and add the powder to the initial stage of the dispersion batches. No weighing step is required as only whole bags are used. The process will be carried out under exhaust ventilation to minimise inhalation and ingestion exposure, and workers carrying out this step will wear personal protective equipment (PPE) including cartridge respirators, gloves, safety glasses and overalls. Maintenance workers changing exhaust ventilation filters will use similar PPE. Inhalation exposure is unlikely in subsequent steps of the formulation process and cleaning of the equipment because the chemical remains in the liquid phase. During these formulation steps involving the liquid phase, workers wear gloves, safety glasses and overalls. The duties of formulation workers vary, and only some workers handle the notified chemical in powder form.
PPE would be used by laboratory staff during testing procedures to reduce dermal and/or inhalation exposure.

Coating of photographic paper
Exposure of workers to the notified chemical will be low during this highly automated process. However, dermal contact may be possible during adjustment of the machines. Gloves are not worn routinely by workers in this area, but additional PPE will be used for procedures where exposure is likely.

End-use of photographic paper
Once the photographic paper has been coated, the notified chemical will covered by other layers and will not be available. No significant dermal or inhalation exposure is expected to workers handling finished photographic paper at the notifier's site or in the production of photographs.

5.4. Release

RELEASE OF CHEMICAL AT SITE
Since the notified chemical will not be manufactured locally, there will be no environmental exposure associated with this process in Australia.

The notifier estimates that 20 kg per year of the chemical will be left as residues in the emptied import bags at the dispersion manufacturing site. Spillage at this stage is stated to be very low as raw material is transferred directly into sealed vessels via special addition ports. The notifier claims that the dust collection filters located above the point where the notified chemical is loaded into the solvent containing vessel are treated as prescribed waste but has not provided the amount of the chemical released trapped in the filters. Based on previous similar assessments, this amount is assumed to be 2 kg per year.

The emptied dispersion containers will be washed with high-pressure water and the washings discharged to the sewer with no discharge through the silver recovery system. This portion of wastewater does not undergo any treatment but is discharged via a hold-up pit (with a capacity of a few thousand litres), where some of the chemicals with low solubility are expected to be deposited. The pit will be cleaned periodically and the contents removed by a contractor for incorporation into concrete blocks for further disposal. The waste stream from cleaning the transfer pipe work and associated equipment connecting the dispersion containers to the coating machine is discharged to the silver recovery process. The notifier estimates a maximum of 3% (480 kg per annum) of the notified chemical to be released via wastewater resulting from these two cleaning processes although part of it is discharged into the silver recovery process. Assuming that all the wastewater is sent to the sewer without treatment, a total of up to 480 kg will be discharged to the Werribee Treatment Plant in Melbourne.

The dispersion manufacture process is expected to generate approximately 1.7% (275 kg) waste, which will be released to the industrial waste system per annum and will be passed through the onsite silver recovery process. The notified chemical contained in the liquid waste is expected to be trapped in the "filter cake" during the silver recovery process, and will be destroyed when the filter cake is shipped to the USA and smelted to recover (or recycle) silver. Based on available data for similar substances treated via similar silver recovery processes, the notifier claims that a removal efficiency of approximately 99.99% can be expected during the silver recovery process. Accordingly, even at the maximum discharge of the notified chemical into the waste stream, less than 1 kg of the notified chemical from the latter source will be released to the sewer via this route per year.

The dispersion manufacturing and coating are batch processes and the notifier has provided the maximum amount of the notified chemical discharged to the sewer assuming no removal via the silver recovery process. A maximum of 4.255 kg will be discharged to the sewer per day. Assuming that the released chemical is received into 450 ML of sewer flow the notifier estimates the concentration of the notified chemical entering the Werribee plant to be 9.45 μg/L.

RELEASE OF CHEMICAL FROM USE

Once coated on the paper and covered with further layers, most of the chemical is expected to be retained in the photographic emulsion, and would consequently be used in minilabs throughout Australia. No release of the chemical is expected during the minilab processing as it will remain bound to the paper.

5.5. Disposal

The residual chemical in empty plastic bags is treated as prescribed waste and is sent to secure landfill. Wastewater resulting from cleaning the dispersion containers will be discharged directly to the sewer without any onsite treatment. Washings from cleaning the pipes and equipment and the wastewater resulting from dispersion manufacture will be sent to the silver recovery system.

Eventual disposal of old photographs is likely to be through deposition into landfill though some old photographs may be incinerated.

5.6. Public exposure

The public will only come in contact with photographic paper coated with the notified chemical. In this form it is covered by other layers and no significant dermal or inhalation exposure is expected.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Beige / brown powder.

Melting Point/Freezing Point 158 to 177°C

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Differential scanning calorimetry (DSC) method used. The endothermic change in enthalpy observed at < 155^{0}C is believed to be a change in crystalline structure.
TEST FACILITY Eastman Kodak (2004a)

Boiling Point Decomposed above 214°C at 6.65 kPa

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks DSC method used. The chemical was tested at reduced pressure because it was expected to decompose prior to boiling at atmospheric pressure. In the testing at reduced pressure, weight loss occurring, suggesting that decomposition had occurred.
TEST FACILITY Eastman Kodak (2004a)

Density 1182 kg/m^3 at 24°C

METHOD OECD TG 109 Density of Liquids and Solids.
Remarks Gas comparison pycnometer method using helium gas.
TEST FACILITY Eastman Kodak (2004b)

Vapour Pressure < 2.6 X 10^{-7} kPa at 25°C

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Vapour pressure balance method used. Measurements were made at several temperatures (between 100-110^{0}C) and linear regression analysis used to estimate vapour pressure at 25^{0}C.
No statistical analyses were performed as the readings were too low and variable for a line of best fit and imposing a regression slope on the reading at 109°C was considered to be more appropriate. This reading was selected as it was the data point that resulted in the highest vapour pressure at any given temperature when a slope of –1500 K was imposed upon the point.
TEST FACILITY Safepharm (2004a)

Water Solubility <5 X 10^{-5} g/L at 25°C

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks The water solubility was measured using the Column Elution Method with HPLC/UV detection.

An instrument detection limit (IDL) standard was prepared from a stock solution of the test substance in 50:50 acetonitrile:2-propanol and diluted with distilled water. The reported IDL was prepared at a concentration of approximately 0.05 mg/L with less than 50:50 acetonitrile:2-propanol.

No test substance peaks were detected in any of the sample chromatograms. The solubility was determined to be less than the IDL.
The test substance is very slightly soluble (Mensink *et al.* 1995).
TEST FACILITY Eastman Kodak (2004c)

Hydrolysis as a Function of pH Not determined.

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.

Remarks Preliminary tests were performed at 50.0 ± 1°C at pH 4, 7 and 9 and at 60.0 ± 1°C at pH 9 with test solutions prepared using a co-solvent (0.5% N,N-dimethylformamide or DMF). The results of HPLC/UV showed that a suitable concentration of the test substance could not be maintained in solution (or suspended). Therefore no further testing was possible.

The notified chemical contains hydrolysable functionalities but this should not occur at ambient conditions in the environmental pH range of 4 to 9.

TEST FACILITY Eastman Kodak (2004d)

Partition Coefficient (n-octanol/water) log Pow > 7.8 at 24 ± 1°C (estimated)

METHOD OECD TG 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks The log Pow was estimated using a reverse phase HPLC separation procedure. A standard (*p*-quaterphenyl) with a known log Pow was prepared and analysed with the test substance. The test substance eluted after the standard (which is the standard with the greatest literature log Pow value).

The high log P_{ow} is consistent with the low water solubility indicating likely partitioning into the octanol phase.

TEST FACILITY Eastman Kodak (2004e)

Adsorption/Desorption log K_{oc}>5.63 (estimated)

METHOD OECD TG 121 Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge Using HPLC.

Remarks The log Koc was estimated using a reverse phase HPLC separation procedure. An estimate of the log Koc was obtained using its experimentally determined retention time using HPLC. This retention time was then compared to that of a reference standard (DDT) with a known log Koc.

The test substance eluted after the standard (which has the highest literature log Koc value). The dead time therefore, was not measured, which deviated from the protocol. This deviation was stated to have had no adverse effects on the outcome of the study.

The high log Koc is consistent with the low water solubility and high log P_{ow} and indicates strong adsorption to and low mobility in soils and sediments.

TEST FACILITY Eastman Kodak (2004f)

Dissociation Constant Not determined

METHOD OECD TG 112 Dissociation Constants in Water.

Remarks Test could not be performed effectively due to the low solubility of the test substance in water and in co-solvents.

The test substance was estimated to have three pKa values (1.1, 7.5 and 13.1) during the adsorption study summarised above (Eastman Kodak 2004f).

TEST FACILITY Eastman Kodak (2004g)

Particle Size

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.
European Commission 1996 Guidance document: Particle Size Distribution Fibre Length and Diameter Distribution.

Range (μm)	*Mass (%)*

< 20	0
20-45	0.06
45-63	0.56
63-75	0.99
75-106	11.61
106-150	27.23
150-212	35.25
212-500	23.35
500-1000	0.63
>1000	0.32

Remarks Dry sieve method.
Mass median diameter 175 μm
Mass mean diameter 199 μm
13.2% by weight of particles were < 106 μm
0.05% by weight of particles were < 45 μm
Under the microscope the particles were seen to be irregularly shaped.
TEST FACILITY Eastman Kodak (2004h)

Flash Point

Remarks Not conducted as notified chemical is a solid.

Flammability Limits Not highly flammable by this test.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks Ignition occurred, indicating that the notified chemical is combustible.
TEST FACILITY Eastman Kodak (2004a)

Autoignition Temperature > 189^0C

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The test substance did not have a relative self-ignition temperature below its melting point.
TEST FACILITY Safepharm (2004a)

Explosive Properties Not expected to be explosive.

Remarks The notifier states that the notified chemical is not explosive under the influence of a flame, based on the results of autoignition temperature testing described above (Safepharm 2004a), and is less sensitive to shock or friction than dinitrobenzene. The heat of decomposition measured by Differential Scanning Calorimetry (DSC) was 297 joules/gram in a melting/boiling temperature test (Eastman Kodak 2004a) and 283 joules/gram in an earlier test (Eastman Kodak 2003h) and is not considered to be explosive.
The notifier also states that structure activity analysis indicates that the notified chemical does not contain highly energetic functional groups that are typical of explosive behaviour.
The MSDS notes that the powdered material may form explosive dust-air mixtures.

Reactivity

Remarks The notifer states that experience in use and structure activity relationships indicate that the notified chemical is not hazardous in contact with air, water or humid air.
MSDS states that the notified chemical is stable under normal conditions. It can decompose at elevated temperatures (Eastman Kodak 2004a). The notified chemical is incompatible with strong oxidising agents. Hazardous polymerisation does not occur. Decomposition products include hydrogen chloride.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	low toxicity: LD50 > 2000 mg/kg bw
Rat, acute dermal	low toxicity: LD50 > 2000 mg/kg bw
Rat, acute inhalation	No data submitted
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – LLNA	no evidence of sensitisation
Rat, repeat dose in diet toxicity – 28 days.	NOAEL 1176 mg/kg bw/day (males) and 1247 mg/kg bw/day (females)
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration	non genotoxic
Genotoxicity – in vivo	No data submitted
Pharmacokinetic/Toxicokinetic studies	No data submitted
Developmental and reproductive effects	No data submitted
Carcinogenicity	No data submitted

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical.

METHOD — OECD TG 420 Acute Oral Toxicity – Fixed Dose Procedure.
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Fixed Dose Method.

Species/Strain	Rat/Sprague-Dawley female.
Vehicle	Doses administered as 20% aqueous suspension in carboxymethylcellulose solution
Remarks - Method	In sighting study 300 mg/kg was first administered to one animal. Data from the sighting study with 2000 mg/kg dosage was combined with data from the 2000 mg/kg main study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
Sighting	1 Female	300	0
Sighting and main	1 Female	2000	0
Main	4 Females	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity	No clinical signs were observed. 4/5 rats gained weight in both weeks of the 14 day observation period. 1/5 rats gained weight overall during the 14-day period, but gained weight during week 1 and lost weight during week 2.
Effects in Organs	No test-related changes were noted at necroscopy.
Remarks - Results	No microscopic examination of tissues was carried out.

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

TEST FACILITY — Eastman Kodak (2004k)

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-Dawley
Vehicle Powder was moistened with water before application.
Type of dressing Occlusive
Remarks - Method At the end of the 4 h exposure period the application site was rinsed with running water.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 male, 5 female	2000	0

LD50 > 2000 mg/kg bw
Signs of Toxicity - Local None
Signs of Toxicity - Systemic None
Effects in Organs No test-related changes were noted at necroscopy.
Remarks - Results No microscopic examination of tissues was carried out.

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

TEST FACILITY Eastman Kodak (2004l)

7.4. 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/Albino (Hra: (NZW)SPF)
Number of Animals 3
Vehicle The solid test substance was moistened with water.
Observation Period 72 h
Type of Dressing Occlusive/Semi-occlusive.
Remarks - Method At the end of the 4 h exposure period the application site was rinsed with running water.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	0	-	0
Oedema	0	0	0	0	-	0

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

Remarks - Results No signs of irritation were evident at any time during the study.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY Eastman Kodak (2003i)

7.5. Irritation - eye

7.5.1 Eye Irritation in vivo

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/Albino (Hra: (NZW)SPF)
Number of Animals: 3
Observation Period: 72 h
Remarks - Method: 0.1g of the notified chemical was administered as received, as a brown powder.
Three additional rabbits were treated similarly, except that the eyes were immediately irrigated with running distilled water.
A preliminary screening test determined that the pH of the test substance (concentration not stated) at 5.5 was not strongly acid or alkaline. As part of the screening procedure, 1/3 rabbits in each group were tested prior to the remaining 2 rabbits.

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	0	0	0	1	1 h	0
Conjunctiva: chemosis	0	0	0	0	-	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 conjunctival redness at 1 h in all unirrigated eyes was the only adverse effect observed. As the study report states that no other lesions or toxicity were observed, it is assumed that no discharge occurred.
2/3 rabbits with eyes washed immediately also showed slight conjunctival redness at 1 h.
Staining was not evident in washed or unwashed eyes when tested with fluorescein dye.

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

TEST FACILITY: Eastman Kodak (2003j)

7.5.2 Eye Irritation in vitro – Irritection Assay System

TEST SUBSTANCE: Notified chemical

METHOD: Irritection Assay System, an in vitro ocular irritation test system.
Remarks - Method: The assay reagent is a highly organised protein matrix. Conformation and hydration changes in contact with an irritant test substance are detected by changes in turbidity and may be relevant to in vivo irritation. Results are calibrated by comparison with standard test substances.
The pH of the notified chemical (10% suspension) was tested to confirm that it falls in the pH 2.0 to 9.0 range, for which the test method is valid.

RESULTS: Irritancy scores were 9.4-11.9 for the notified chemical.
The pH of a 10% suspension was 5.5.
Remarks - Results: The irritancy scores obtained fall into the minimally irritant category (0.0-12.5) under the Irritection Draize Equivalent scoring system.

CONCLUSION: Test results suggest that the notified chemical may have the potential to produce, at most, minimal eye irritation.

TEST FACILITY: Eastman Kodak (2003k)

7.6. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 429: Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse (CBA/CaJ) female.
Vehicle	Acetone/olive oil (4:1 v/v), also used for positive control.
Remarks - Method	For primary irritation screen, 25% and 50% of the test substance were each applied to 2 animals. For the main sensitisation study 5 animals/group were used with a total of 5 groups: vehicle control, positive control, and 10%, 25% and 50% of the test substance. Lymph node cells from each group were pooled before analysis. The positive control used was 25% hexyl cinnamic aldehyde.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	1983	1.00
10	2224	1.12
25	1769	0.89
50	2106	1.06
Positive Control		
25%	5607	2.83

Remarks - Results	No irritation was noted during the primary irritation screening or in the test groups, except for very slight erythema in some animals in the positive control group. The response in all test substance groups was slight, with the stimulation indices close to that of the vehicle control, and no dose response relationship was found. The stimulation index for the positive control hexyl cinnamic aldehyde was substantially above the vehicle control but less than 3. The study author states that the positive control result of 2.83 falls within the reported stimulation index range of 2.4-6.0 reported for this chemical by Basketter et al (1993).
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	Eastman Kodak (2004m)

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	Rats, Sprague-Dawley
Route of Administration	Oral –diet.
Exposure Information	Total exposure days: 28 days (male); 29 days (female) Dose regimen: 7 days per week; Post-exposure observation period: nil
Vehicle	Mixed with ground certified chow.
Remarks - Method	Dosage for the main study was chosen on the basis of a 7-day preliminary

study using 0, 5, 10 and 15 mg/g of the notified chemical in food.

RESULTS

Group	*Number and Sex of Animals*	*Dose/Concentration*		*Mortality*
		Nominal in food mg/g	*Actual dose mg/kg/day*	
I (control)	5 male, 5 female	0	0 m, 0 f	0
II (low dose)	5 male, 5 female	1.5	117 m, 128 f	0
III (mid dose)	5 male, 5 female	4.5	346 m, 367 f	0
IV (high dose)	5 male, 5 female	15.0	1176 m, 1247 f	0

Mortality and Time to Death
No mortality occurred during the study.

Clinical Observations
In the functional observational battery (FOB) on day 22, an abnormally high value of constricted pupil size in the male control group was the cause of an apparently low constricted pupil size in all other male groups. No other test related clinical abnormalities were noted, including body weight, body weight gain and feed consumption.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No significant differences were noted for haematology parameters in any group. Statistically significant lower mean albumin/globulin ratios were observed in low dose female rats only but were within historical controls. No other changes in clinical chemistry parameters were noted.

Effects in Organs
Significantly higher spleen weights (absolute and relative to body weight) were noted in the low dose and high dose female groups but not the corresponding mid dose female group.
Macroscopic examination was carried out on organs of all groups, and microscopic examination was carried out on the controls and the high-dose animals. Macroscopic and microscopic changes were detected in a number of organs, including spleen, thymus, lungs, heart, uterus and liver. Most but not all microscopic effects were rated as minimal or mild and were seen to some extent in both control and high dose animals. For some effects, the ratings of severity were higher for test animals, and for other effects were higher for control animals.

Remarks – Results
The study authors did not consider any pathological changes to be test substance related. Lung and thymus effects were considered agonal. All others were scattered or common effects, and no dose response effect was observed. Clinical chemistry changes were not dose related and were within historical controls.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 1176 mg/kg bw/day for male rats and 1247 mg/kg bw/day in this study, based on the absence of significant effects at the highest dose tested.

TEST FACILITY Eastman Kodak (2004n)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE

METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*:WP2uvrA (pKM101).
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Concentration Range in	a) With metabolic activation: 10-5000 µg/plate.

Main Test	b) Without metabolic activation: 10-5000 µg/plate.
Vehicle	Dimethyl sulfoxide (DMSO).
Remarks - Method	Test 2 for TA98 in the absence of S9 was invalidated by a high mean vehicle control and was repeated in a third test. The results of the third test have been entered in the table below under "Test 3".

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000 µg/plate	> 1000 µg/plate for WP2uvrA (pKM101)	Obscured plates at > 1000 µg/plate.	negative
Test 2*	-	> 1000 µg/plate for WP2uvrA (pKM101)	Obscured plates at > 1000 µg/plate.	negative
Test 3*	-	> 5000 µg/plate for TA98.	Obscured plates at > 1000 µg/plate.	negative
Present				
Test 1	> 5000 µg/plate	> 5000 µg/plate	Obscured plates at > 1000 µg/plate.	negative
Test 2	-	> 5000 µg/plate	Obscured plates at > 1000 µg/plate.	negative

* TA98 was evaluated in test 3. The other strains were evaluated in test 2.

Remarks - Results	The number of revertants for TA100 at 5000 µg/plate with S9 in test 2 was higher than the other readings (143 vs vehicle control 108). However the result is not considered significant because this value was within the range of the vehicle controls (52-149), did not appear to be dose-related and similar effects were not seen in TA100 with S9 in test 1 or the preliminary study. Negative controls for all groups were within historical limits. Positive controls confirmed the sensitivity of the test system.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test
TEST FACILITY	Covance Laboratories (2004a)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE

METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line	Chinese Hamster ovary (CHO) cells / DCHO-WBL cell line.
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver and NADP + isocitric acid (energy producing system).
Vehicle	Dimethyl sulfoxide (DMSO).
Remarks - Method	Little cytotoxicity was found at the doses tested, with only minor or no reduction of the mitotic index observed even at the highest doses. However the highest dose tested (400 µg/mL) was above the solubility limit of the notified chemical after dosing.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	32.9, 47.1, 67.2, 96.0*, 137*, 196*, 280, 400*	3 h	20 h

Test 2	6.25, 12.5, 25.0*, 50.0*, 100*, 150*, 225, 300, 400	3 h	20 h
Present			
Test 1	32.9, 47.1, 67.2, 96.0*, 137*, 196*, 280, 400*	3 h	20 h
Test 2	50.0*, 100*, 150*, 225*, 300*, 400*	17.8 h	20 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 200 µg/mL	> 400 µg/mL	≥ 196 µg/mL	not observed
Test 2	-	> 400 µg/mL	> 400 µg/mL	not observed
Present				
Test 1	> 140 µg/mL	> 196 µg/mL	≥ 196 µg/mL	not observed
Test 2	-	> 225 µg/mL	≥ 150 µg/mL	not observed

Remarks - Results The sensitivity of the system was confirmed with positive and negative controls.

CONCLUSION The notified chemical was not clastogenic to Chinese Hamster Ovary (CHO) cells treated in vitro under the conditions of the test.

TEST FACILITY Covance Laboratories (2003a)

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 (Modified Sturm Test). Part C.4-C, Determination of Ready Biodegradability
Inoculum	Activated sludge from a domestic wastewater treatment works
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved organic carbon (DOC)
Remarks - Method	In addition to the test substance at 30.5 mg/L (20 mg/L DOC), blank samples and samples containing a reference substance (sodium benzoate) at 34.3 mg/L (20 mg/L DOC) were measured.

RESULTS

	% Degradation		
Day	*Test substance Vessel #1*	*Test substance Vessel #2*	*Sodium benzoate*
8	3	-1	47
14	3	-1	54
20	3	-1	58
28	4	-1	62

Remarks - Results	The reference substance attained a maximum level of biodegradation of 62% validating the test conditions.
CONCLUSION	The test substance is not readily biodegradable according to the OECD criteria requiring > 60% within 10 days of commencement.
TEST FACILITY	Eastman Kodak (2003e)

8.1.2. Bioaccumulation

No bioaccumulation data were provided. The low water solubility and the high estimated log Pow of the notified chemical indicate a potential for bioaccumulation.

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

TEST SUBSTANCE	Notified chemical
METHOD	Method C.5 Degradation, biochemical oxygen demand, Official Journal of the European Communities, No. L251/212
Inoculum	Not provided.
Exposure Period	Not provided.
Auxiliary Solvent	Not provided.
Analytical Monitoring	Not provided.
Remarks – Method	The report does not provide the details of the method except that no protocol deviations were made during the study.
Remarks – Results	No results were provided. The BOD could not be determined due to the low water solubility of the test substance. The BOD_5/COD could not be calculated.
CONCLUSION	The BOD could not be determined due to the low water solubility of the test substance.
TEST FACILITY	Eastman Kodak (2004j)

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test and EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - Static
Species	Fathead Minnows *(Pimephales promelas)*
Exposure Period	96 hours
Auxiliary Solvent	N,N-dimethyl formamide (DMF)
Water Hardness	Not provided.
Analytical Monitoring	High performance liquid chromatography with ultra-violet detection (HPLC/UV).
Remarks – Method	The water solubility of the test substance measured using HPLC/UV, was determined to be less than 0.05 mg/L. Therefore, the stock solutions of the test substance were prepared at 10 mg/mL with DMF and the 1 mg/L test solution was prepared by diluting 2 mL of stock solution with 20 L laboratory dilution water. Solvent control solutions were prepared by diluting 2 mL of DMF with 20 L laboratory dilution water. Samples of the control and test solutions were collected from approximately mid-depth of test vessels individual replicate at the start and end of test to verify concentrations. The measured concentrations of individual replicates (at the beginning and end) were geometrically averaged and then arithmetically averaged to determine a combined exposure concentration. The control and test substance solutions appeared clear and colourless throughout the study. Oxygen content (6.8 to 8.9 mg/L in controls and 6.8 to 8.8 mg/L in test substance solutions) and temperature (20°C) were satisfactorily maintained. The pH of the test and control solutions ranged from 8.1 to 8.6, which is higher than the recommended range from 6.0 to 8.5 but was acceptable.
RESULTS	
LC50	> 0.95 mg/L (highest test concentration) at 96 hours.
NOEC	0.95 mg/L (highest test concentration) at 96 hours.
Remarks – Results	No mortalities or behavioural effects were observed in the control or test solutions during the study period. The test concentrations of the two replicates during the study period were 0.94 mg/L and 0.95 mg/L (with 8.9% and 10.9% test substance concentration lost, respectively). The average exposure concentration was calculated to be 0.95 mg/L (greater than the water solubility of the test substance).
CONCLUSION	The test substance is not toxic to fish up to the limit of its water solubility.
TEST FACILITY	Eastman Kodak (2003f)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test

	EC Directive 84/449/EEC C.2 Acute Toxicity for Daphnia and – Static Test
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	DMF
Water Hardness	Not provided.
Analytical Monitoring	HPLC/UV
Remarks - Method	The water solubility of the test substance measured using HPLC/UV, was determined to be less than 0.05 mg/L. A 200 mL aliquot removed from each of the treatment solutions for the fish toxicity study (summarised under 8.2.1) was used in the concurrently run daphnid study. Test concentrations were verified using the same method as described in the fish study. The control and test substance solutions appeared clear and colourless throughout the study. Oxygen content (8.6 to 8.9 mg/L in controls and 8.5 to 8.8 mg/L in test substance solutions), pH (8.5 to 8.6 in controls and 8.4 to 8.6 in test substance solutions) and temperature (20°C) were all satisfactorily maintained. Assessments of daphnia immobilisation and behavioural abnormalities were made at test start, after 4 hours and at the end of each 24 hours.

RESULTS

LC50	> 0.92 mg/L (highest test concentration) at 96 hours.
NOEC	0.92 mg/L (highest test concentration) at 96 hours.
Remarks - Results	No immobilisation or behavioural effects were observed in the control or test solutions during the study period. The test concentrations of the two replicates during the study period were 0.91 mg/L and 0.93 mg/L (with 14.3% and 14.9% test substance concentration lost, respectively). The average exposure concentration was calculated to be 0.92 mg/L (greater than the water solubility of the test substance).

CONCLUSION	The test substance is not toxic to daphnia up to the limit of its water solubility.
TEST FACILITY	Eastman Kodak (2003g)

8.2.4. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Nominal	1.0 mg/L
Concentration Range Actual (Geometric mean)	0.88 mg/L
Auxiliary Solvent	DMF
Water Hardness	Standard test medium was used.
Analytical Monitoring	HPLC with Diode Array Detection (DAD)
Remarks - Method	The water solubility of the test substance measured using HPLC/UV, was determined to be less than 0.05 mg/L. A stock solution was prepared by diluting 0.1006 g of test substance in a 10 mL volumetric flask to volume with DMF. The limit test exposure solution (of 1.01 mg/L) was prepared

by adding 100 µL of the stock solution to 999.7 g sterile medium.

Five replicates with test solutions (including 2 with no algae added but serving as light-exposed and light-shaded chemical controls), six control replicates (including 3 solvent controls with DMF added) were tested.

At test start and after 24 hours, the flasks containing the test substance and medium control flasks were clear and colourless in appearance. After 48 hours test solution as well as the solvent and medium controls were slightly green in appearance. The test solution flasks and medium and solvent control flasks appeared green at the end of the test but the light and dark chemical controls were clear and colourless throughout the test.

The initial cell concentration was 1 X 10^4 cells/mL and the pH and temperature were maintained satisfactorily during the test period. Test substance concentration in the exposure solutions and the chemical controls were measured at 0, 24, 48 and 72 hours.

RESULTS

Growth - E_rC50	*Biomass - E_bC50*	*NOEC*
mg/L (0- 72 h)	*mg/L (0- 72 h)*	*mg/L at 72 h*
>0.88	>0.88	0.88

Remarks - Results

The water solubility of the test substance was determined to be less than 0.05 mg/L.

The loss of the test substance concentration from flasks containing algae was determined to be 33.0% while the losses in chemical control flasks (without algae) were lower (8.5% in the light-exposed flasks and 4.7% in the light-shielded flasks). This suggests that some of the test substance may have been adsorbed to the algae. The growth curve for test substance was very similar to those of the controls, which exhibited normal log growth. Both the E_bC50 and E_rC50 values are greater than the measured water solubility of the test substance.

CONCLUSION

The test substance is not toxic to algae up to the limit of its water solubility.

TEST FACILITY

Eastman Kodak (2004i)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Most of the notified chemical is expected to be retained in the photographic emulsion, and would consequently be dispersed widely through use in minilabs throughout Australia. Release of the chemical during the minilab processing is unlikely, as it will remain bound to the paper. Eventual disposal of old photographs is likely to be through deposition into landfill where very slow release could be expected as the paper and the emulsions are degraded. Some old photographs may be incinerated, which would destroy the chemical, producing water vapour and oxides of carbon and nitrogen and hydrogen chloride.

The notified chemical that will be left in emptied import bags as residue (20 kg per annum) and trapped in the dust extraction filters (about 2 kg per year) will also be disposed to landfill. The high estimated log Koc and the low water solubility indicate strong adsorption to soils and sediments and low mobility in both the aquatic and terrestrial compartments. It also has a high estimated log Pow. Therefore, the notified chemical has a potential to adsorb to particulate organic material and soil and accumulate in sediments due to sorption and settlement. It is not readily biodegradable, however, when disposed in landfill the chemical will eventually degrade through slow biological and abiotic processes.

A worst-case scenario is considered assuming that all of the liquid waste containing the notified chemical resulting from the dispersion manufacturing and transfer processes will be discharged to the sewer without undergoing the silver recovery process. A maximum of 755 kg per annum was estimated (as a worst-case) to be discharged into the Melbourne sewage system and subsequently enter the Werribee sewage treatment plant. The predicted environmental concentration (PEC) likely to enter the Werribee plant is estimated as follows:

Average total inflow to the Werribee treatment plant = 500 ML/day
= 500 X 10^6 X 365 L/year
PEC expected in inflow to the Werribee plant = 755 kg/500 X 10^6 X 365 L
= 4.14 µg/L

If it is further assumed that the notified chemical that enters the Werribee plant will not be removed during sewage treatment processes, worst-case PECs of the notified chemical in the treatment plant effluent and in marine water (when discharged in to the ocean subsequently) may approximate 4.14 µg/L and 0.41 µg/L (based on a dilution factor of 10 for ocean discharge of effluents), respectively.

The above scenario assumes that the notified chemical is released via the Werribee plant into the ocean at a constant daily rate throughout the year. In reality, the discharge of the notified chemical will not be constant as the chemical is used in a batch-processing situation. Therefore, another worst-case scenario is considered using the PEC estimate of 9.45 µg/L (based on batch processes) provided by the notifier. If it is assumed that the sewage treatment processes at the Werribee plant will not remove the notified chemical, the worst-case PECs of the notified chemical in the treatment plant effluent and in marine water (when discharged in to the ocean subsequently) may approximate 9.45 µg/L and 0.95 µg/L (based on a dilution factor of 10 for ocean discharge of effluents), respectively.

There is potential for the notified chemical to bioaccumulate due to its high log P_{ow} and the low water solubility.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests are listed below. The most sensitive species was algae with 72 hour EC50 and EbC50 values of >0.88 mg/L.

Organism	*Duration*	*End Point*	*mg/L (Measured)*
Fish	96-h	LC_{50}	>0.95
Daphnia	48-h	EC_{50}	>0.92

Algae	72-h	E_bC_{50}	>0.88
		E_rC_{50}	>0.88

A predicted no effect concentration (PNEC - aquatic ecosystems) of >8.8 X 10^{-3} mg/L (>8.8 μg/L) has been derived by dividing the end point of >0.88 mg/L by a worst-case scenario uncertainty (safety) factor of 100 (as toxicity data are available for three trophic levels).

9.1.3. Environment – risk characterisation

A risk quotient value for marine water (Q_{Marine} = PEC_{Marine}/PNEC) of < 0.05 was predicted for the worst-case scenario based on the annual release estimates mentioned above. The Q_{Marine} value for marine environment calculated based on the notifier provided daily release concentrations of the chemical is <0.11. Both these values indicate no immediate concern to the aquatic compartment. Further, a part of the notified chemical which can be expected to be removed during the in-house silver recovery process (up to 99.99% as the notifier claims), has not been considered during both these scenarios. This reduction in the chemical concentration in the discharge into the Werribee plant and some adsorption of the chemical to sludge during sewage treatment (as indicated by the high estimated log Pow and low water solubility) can be expected to further reduce the PEC_{Marine} and Q_{Marine} values.

The low water solubility and the high estimated log Pow of the notified chemical indicate a potential for bioaccumulation. High peaks of concentration may result due to the batch processing nature of chemical use and single point discharge. The effluent released from the Werribee plant moves via several ponds and passes grassed areas prior to discharging into the ocean. It is expected that a considerable amount of the notified chemical will be settled into sediments in these ponds and filtered by grass. Therefore, the chemical is not expected to be present in the ocean water at levels which can result in bioaccumulation.

Based on the proposed use pattern the notified chemical is not expected to pose an unacceptable risk to the health of aquatic life. However, if the notified chemical is used in other locations without the huge dilution capacity and tertiary treatment processes similar to those available in the Werribee treatment plant, a secondary notification to reassess hazard and bioaccumulation potential will be required.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Workers are potentially exposed to the notified chemical during the production and application of a coating for photographic paper. The highest potential for exposure occurs at the initial stages of the dispersion formulation process, when the notified chemical in powder form is incorporated into a liquid pre-mix, and during maintenance work on the local exhaust ventilation system in this area. The powder was found to contain approximately 13.2% of particles by weight in the inspirable range (< 100 μm) but none in the respirable range (< 10 μm). The extent of handling of the notified chemical in powder form will be reduced because whole bags of the chemical are added to batches, with no weighing stage required. Inhalation, ingestion, dermal and ocular contact are all possible at this stage, however the use of engineering controls and PPE will further minimise the potential exposure.

Dermal and ocular exposure to workers is possible at subsequent stages of the formulation process and during the automated coating operation. It is expected that any exposure would arise from accidental splashes and spills in the formulation area, or trouble-shooting work on the production line. Appropriate PPE will be used by workers to minimise any dermal or ocular exposure.

Once the notified chemical is incorporated into the photographic paper coating, and covered by subsequent layers, inhalation or dermal contact should not occur. Therefore no significant exposure is expected to workers handling photographic paper.

9.2.2. Public health – exposure assessment

The public is not expected to come in contact with the notified chemical, except as a coating component of photographic paper, in which it is bound to the substrate and covered by overcoat layers. In this form, the potential for dermal or inhalation exposure is considered to be very low. The possibility of public exposure with accidentally spilt material is also considered very low.

9.2.3. Human health - effects assessment

The notified chemical is of low acute oral and dermal toxicity. Acute inhalation toxicity testing was not carried out. It is non-irritating to rabbit skin, and only minimally irritating to the eye when tested on rabbits and by the in vitro Irritection Assay. It is not a skin sensitiser, based on the results of the local lymph node assay (LLNA). Although this test gave lower than expected results for the positive control, these results were within historical limits.

In a 28-day repeat dose feeding study in rats using up to an average of 1200 mg/kg bw/day, no significant changes were detected that were considered test related. Therefore the NOEL was set at 1176 mg/kg bw/day for males and 1247 mg/kg bw/day for females, the highest dosages tested.

The notified chemical was not genotoxic in the presence or absence of metabolic activation in either a bacterial reverse mutation test or a chromosome aberration test. However the chromosome aberration test could not be carried out at concentrations that would cause significant cytotoxicity, because of the low solubility of the notified chemical in the vehicle. Therefore this test was not carried out under optimal conditions for detecting chromosomal aberrations.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2002).

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is imported in powder form, and incorporated in a dispersion formulation, which forms one of several layers applied to photographic paper. In the initial stages of dispersion manufacture, there is the potential for inhalation or ingestion exposure to the notified chemical, as well as dermal and ocular exposure. In the later stages of dispersion manufacture and in the automated coating process, there is the potential for incidental dermal and ocular exposure. It is expected that the planned engineering and PPE controls will reduce the extent of any exposure.

Because the notified chemical is covered by other layers in the final photographic paper, no significant worker exposure to the chemical is expected as a result of handling photographic paper.

Based on available animal testing, the acute and chronic health effects of the chemical are expected to be low.

Overall the risk to workers is considered low, based on low hazard and the planned engineering controls for the formulation and coating processes.

9.2.5. Public health – risk characterisation

The public is not expected to have contact with the notified chemical, except in the case of accidental release during transport. The public will have contact with coated photographic paper containing the chemical, but it will be bound under the outside layers of the paper. The risk to the public is considered very low, because of low hazard and low exposure.

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

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

According to the GHS criteria, the notified chemical is classified as Chronic Category 4 (may cause long lasting harmful effects to aquatic life). It is not classified on the basis of human health effects.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio the notified chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used as a component of the coating for photographic paper.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - For formulation, local exhaust ventilation should be used when handling the notified chemical in powder form.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced and in the dispersion formulation and application processes:
  - In handling the notified chemical, avoid spills and dust generation.
  - In handling the notified chemical, minimise the potential for ingestion through good personal hygiene.
  - In handling the dispersion formulation, avoid spills, splashes or aerosol generation

that would increase exposure.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and in the dispersion formulation and application processes:
  - Respiratory protection if exposure to dust is likely
  - Gloves
  - Protective clothing
  - Safety eye protection

  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.

Environment

Disposal

- Residual chemical retained in emptied containers and in dust collection filters should be treated as prescribed waste and disposed of to secure landfill. Follow label warnings even after container is emptied.

Emergency procedures

- Spills/release of the notified chemical should be handled by shovelling into suitable containers for disposal. Avoid dust formation. Clean surface thoroughly to remove residual contamination.

12.1. 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(1) of the Act; if
  - the notified chemical is used in other locations, that do not have similar huge dilution capacity and tertiary treatment processes to those available in the Werribee treatment plant. In such circumstances, a secondary notification to reassess hazard and bioaccumulation potential is likely to be required.

or

(2) 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.

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