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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

B-21825

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Kodak Australasia Pty Ltd (ACN 004 057 621, ABN 49 004 057 621)
173 Elizabeth St
Coburg, Victoria 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 identity
Details of overseas notifications
Import volume
Specific use
Details of process and release.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Flash point
Autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
LVC Permit No. 591 (2004)

NOTIFICATION IN OTHER COUNTRIES
USA (1995, 1997), EU (1995), Canada (1997, 1998).

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
C-1744, 10096569

MARKETING NAME(S)
B-21825

SPECTRAL DATA

ANALYTICAL METHOD	IR, UV-visible, ^{1}H NMR
Remarks	Spectra and test reports were provided.
TEST FACILITY	Eastman Kodak (1994a, 1994b, 1994c, 2003a, 2003b, 2004a)

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	HPLC/UV, GC/FID
TEST FACILITY	Eastman Kodak (1994d, 2003c)

3. COMPOSITION

DEGREE OF PURITY
98 - 100% (individual batches 98.5% and 98.9%).

HAZARDOUS IMPURITIES
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
None

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported

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

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

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 air, and transported to the notifier's warehouse. Packaging of the chemical consists of polythene bags within foil bags, contained in cardboard fibre drums.

5.2. Operation description

The notified chemical will be stored the notifier's warehouse before use in a multi-stage batch process, as part of the manufacture of a coating layer for photographic paper. In the first step a quantity sufficient for one batch will be pre-weighed and mixed into a slurry. The slurry will be stored in a closed container and used in another production area as one component of a emulsion. The emulsion mix will be stored and incorporated as needed in the coating formulation. Application of the coating to photographic paper will be a highly automated process. Once incorporated into the paper coating, the notified chemical will be covered by other layers and become part of the paper article. The paper will be sold to photo-processors and used to produce photographic prints.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Weighing / formulation workers	12	0.5 hours/day	250 days/year
Emulsion formulation	15	0.5 hours/day	250 days/year
Laboratory workers	3	0.5 hours/day	250 days/year
Maintenance workers	1	2 hours/week	1 week/year
Operators in application of coatings	< 20	intermittent	infrequent

EXPOSURE DETAILS

Transport and storage
Transport and storage workers, including transport drivers and warehouse workers will handle sealed cardboard boxes, containing double-wrapped inner packages of the notified chemical. Warehouse workers may also handle the sealed inner packages. No exposure is expected unless the packaging is accidentally breached.

Weighing and formulation
Formulation workers will weigh batch quantities of the notified chemical under exhaust ventilation, in order to reduce inhalation and ingestion exposure, however skin contact with the powder may occur. The notified chemical will then be incorporated in a slurry within a 4 L plastic bottle, and transferred to a different formulation area. A multi-stage formulation process will incorporate the slurry into a photographic emulsion that is stored before use in the paper coating process. Formulation workers and maintenance personnel potentially exposed to the notified chemical in powder form are expected to use respiratory protection, as well as the gloves, safety glasses and overalls worn by all formulation workers. Once the notified chemical is incorporated into the slurry, and later into the emulsion, inhalation exposure should not occur. However, dermal/ocular exposure to the liquid formulation may occur through spills, splashes or drips, or through cleaning processes. Potential exposure is reduced because the latter stages of the formulation process are automated.
Suitable personal protective equipment (PPE) would also be worn by laboratory personnel during testing of the chemical, slurry and emulsion.

Coating of photographic paper
Exposure of workers to the notified chemical during the coating process is expected to be low because the process is highly automated. Dermal contact can occur during adjustment of machines and maintenance work. Although gloves are not routinely worn in this area, additional PPE is used where exposure is likely.

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

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. Environmental release of the notified chemical is unlikely during importation, storage and transportation, and accidental spills, leaks and catastrophic mechanical failure during a transport accident are the most likely reasons for environmental release. The notified chemical will be transported by road directly from the point of import to the notifier's facility. The notified chemical is imported in a solid form and has some water solubility. Engineering controls such as container specifications, personnel training, storage requirements and emergency clean-up procedures (ie. spill response instructions on Material Safety Data Sheet and label) will limit the impact on the environment of such incidents. The imported chemical will be contained in a 1 kg sealed, black conductive polythene bag, which is inside a foil-lined, sealed bag within a 4 gallon sealed, labelled fibre box. There is no anticipated environmental release during transportation or storage.

The notified chemical is blended with other constituents into a batch emulsion of < 5 g/L before application to paper articles via a closed, automated application system. There are no anticipated releases to the environment of the pure chemical and no waste is routinely generated during solution preparation. Any chemical released from the automated processing equipment is collected for wastewater treatment. Wastes from the emulsion will be treated at an on-site industrial wastewater treatment plant (WWTP), with treated effluent sent to sewer for further treatment and eventual release to the aquatic environment. Filtercake generated in the WWTP is thermally treated overseas resulting in the thermal destruction of the notified chemical and no local release. Based on a site dilution factor of 1:10000, release of the notified chemical to sewer in site effluent has been estimated by the notifier at <0.01% (<0.02 kg/y) of the total import quantity (site sewerage 0.4 ML/d). This effluent mixes with a further 500 ML/d within the sewerage system, potentially with a concentration of $<10^{-4}$ µg/L assuming no attenuation other than dilution.

Emptied imported containers are estimated to contain <1% (<1.6 kg/y) of the notified chemical in residues. These containers are sent to secure landfill for disposal.

RELEASE OF CHEMICAL FROM USE
Once applied and cured, the notified chemical will bind to the applied articles with no potential for environmental release. The printed articles containing the notified chemical are likely to be stored by customers and unlikely to be released to the environment.

5.5. Disposal

Aqueous wastes from use of the notified chemical will be treated prior to sewer disposal, with filtercake residues exported for thermal treatment resulting in the formation of oxides of carbon, and potentially oxides of nitrogen, sulphur and hydrogen chloride. Residues in emptied containers will be sent to secure landfill for disposal (<1.6 kg/y). The notified chemical will be stored by the user and bound under overcoat in printed paper products. Eventually most will be sent to landfill for disposal or recycled as paper wastes.

5.6. Public exposure

Once the notified chemical has been applied to photographic paper as part of the coating, it will be covered by other layers and will not be available. Therefore no significant dermal or inhalation exposure to the public is expected.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Yellow powder / solid

Melting Point/Freezing Point 191°C (decomposes prior to melting)

METHOD	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	The notified chemical decomposes from approximately 191°C, and forms a black, viscous liquid at approximately 292 to 296°C.
TEST FACILITY	Safepharm (1995)

Boiling Point

Remarks	Not conducted

Density 1449 kg/m^3 at 24°C

METHOD	in latter stages of the formulation OECD TG 109 Density of Liquids and Solids.
Remarks	Helium pycnometer method used.
TEST FACILITY	Eastman Kodak (2004b)

Vapour Pressure < 7.6 x 10^{-8} kPa at 25°C

METHOD	EC Directive 92/69/EEC A.4 Vapour Pressure (Vapour Pressure Balance).
Remarks	Actual readings were carried out at 171-181°C, and were too low and variable to carry out statistical analyses. The final result was taken from a regression slope on a chosen data point, from the trial where degassing of the solid was considered to be most complete.
TEST FACILITY	Safepharm (2003)

Water Solubility 4.118 g/L at 25°C (4.118 g/L ± 0.161 (±SD) at 25°C)

METHOD	OECD TG 105 Water Solubility.
Remarks	Solubility in distilled water was determined with the Flask Method. Analysis of the dissolved material was carried out by HPLC, and showed that almost all the

dissolved material was eluted in a single peak.

TEST FACILITY Eastman Kodak (1994e)

Hydrolysis as a Function of pH

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

pH	*T (°C)*	*t½ days*
4	25°C	75
7	-	Not calculated
9	-	Not calculated

Remarks Preliminary and definitive tests were performed at pH 4, 7 and 9 (50°C). Stock solution was prepared by addition of test material (0.03-0.04 g) in 100 mL flask and filled with 50:50 dimethylformamide (DMF):high purity water. Working test solutions were prepared by diluting 1.0 mL aliquots to 50 mL with respective pH buffers. Final working concentrations were ~7 mg/L with 1% DMF. These were held for 5 days between 50-80°C and extrapolated to 25°C. All test systems were clear and yellow with no visible test substance. Aliquots were sampled for analysis by HPLC/VIS.

TEST FACILITY Eastman Kodak (2004e)

Partition Coefficient (n-octanol/water) Log Pow = 2.0 at 25°C

METHOD USEPA Test Guideline 796.1570 (HPLC Method/Flask Method): Partition Co-efficient (n-Octanol/Water) and OECD TG 117 Partition Co-efficient (HPLC).

Remarks Estimated using an empirically derived using the following equation that relates Pow to experimentally determined retention time using HPLC:
Log Pow = (m x log k) + b (where m = slope, b = y-intercept, k = 3.1608 = capacity factor based on acetone retention time).

TEST FACILITY Eastman Kodak (1995).

Adsorption/Desorption log Koc = <1.25 at 23°C

METHOD OECD TG 121 Estimation of the Adsorption Coefficient (Koc) on Soil and Sewage Sludge using High Performance Liquid Chromatography (HPLC).

Remarks The Standard and test substances were dissolved in methanol, at working concentrations of ~200 mg/L and 200 mg/L, respectively. Samples were analysed by HPLC/UV. The test substance eluted before the acetanilide standard, which is the standard having the lowest literature Log Koc value, therefore the Log Koc of the test material was estimated to be <1.25. This is the value for its ionised form.

TEST FACILITY Eastman Kodak (2004f)

Dissociation Constant pKa could not be determined.

METHOD OECD TG 112 Dissociation Constants in Water.

Remarks Titration with sodium hydroxide and hydrochloric acid solutions did not give significantly different results from titration with water. Estimation of pKa values was not carried out.
The dissociation constant of the test material could not be determined using OECD TG 112. Titrations of solutions containing the test material dissolved in water, using both basic (sodium hydroxide) and acidic (hydrochloric acid) titrants did not show any significant differences from titrations of blank water. The notified chemical is a very strong acid that will remain dissociated throughout the environmental pH range of 4-9.

TEST FACILITY Eastman Kodak (2004c)

Particle Size

METHOD OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (μm)	*Mass (%)*
< 20	0
20-45	0.01
45-63	0.01
63-75	0.03
75-106	0.18
106-150	2.56
150-212	15.01
212-500	69.03
500-1000	9.23
> 1000	3.94

Remarks A sieve method was used to determine particle size. The chemical was observed under a microscope to consist of yellow/green irregularly shaped rectangular particles, with a tendency to clump together, even after drying in a 110°C oven for approximately five minutes. Results reported above are an average of three trials on the same sample.
Mass median diameter was 390 μm (standard deviation 51.8) and mass mean diameter 361 μm (standard deviation 35.7).
0.24% by weight of particles were < 106 μm diameter.
0.01% by weight of particles were < 45 μm diameter.

TEST FACILITY Eastman Kodak (2004d)

Flash Point

Remarks Not conducted as notified chemical is a solid.

Flammability Not highly flammable.

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks During the test the substance ignited, indicating that it is combustible. It burnt with a small yellow flame that emitted grey/black smoke and left black and charred remains.

TEST FACILITY Safepharm (1994)

No ignitable gases evolved on contact with water.

METHOD EC Directive 92/69/EEC A.12 Flammability (Contact With Water).
Remarks The test substance did not evolve gas in any of the four procedures of the test.
TEST FACILITY Safepharm (1994)

Not pyrophoric.

METHOD EC Directive 92/69/EEC A.13 Pyrophoric Properties of Solids and Liquids.
Remarks The test substance did not ignite under the conditions of the test.
TEST FACILITY Safepharm (1994a

Autoignition Temperature Autoignition did not occur below the melting temperature.

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks A sample of the notified chemical was heated to 311°C, approximately 10°C higher than the melting temperature determined in a preliminary test. In another melting point determination (Safepharm 1995a) the notified chemical decomposed from approximately 191°C, and formed a black, viscous liquid at approximately

292 to 296°C.

TEST FACILITY Safepharm (2003)

Explosive Properties Not expected to be explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.

Remarks The results of flammability testing above (Safepharm 1994a) indicate that the chemical is not explosive under a flame.
The notifier advised that the notified chemical is less sensitive to shock and friction than dinitrobenzene.
The notifier also advised that structure activity analysis of the notified chemical indicates that it does not contain highly energetic functional groups typical of explosive behaviour.
The heat of decomposition was determined to be 175 joules/gram by differential scanning calorimetry (DSC) (Eastman Kodak 1994f).
While there is no information from testing or experience to suggest that the notified chemical is a dust explosion hazard, caution is warranted because many organic dusts form explosive mixtures with air.

Reactivity

Remarks The notifier states that the notified chemical is not known to possess oxidising properties, and does not contain reactive functional groups typical of oxidising compounds. It is stated to be incompatible with strong oxidising agents.
The notified chemical can decompose at elevated temperature (Safepharm 1995a).
The MSDS states that it is stable under normal conditions, and hazardous polymerisation does not occur. Hazardous decomposition products include oxides of nitrogen, oxides of sulfur and hydrogen chloride.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rat, acute inhalation	not tested
Rabbit, skin irritation	non-irritating
Eye irritation – In vivo rabbit	slightly irritating
Eye irritation - In vitro EYTEX bioassay	minimally irritating
Guinea pig, skin sensitisation – adjuvant test (GPMT)	no evidence of sensitisation.
Rat, repeat dose toxicity.	not tested
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro	not tested
Genotoxicity – in vivo	not tested
Pharmacokinetic/Toxicokinetic studies	not tested
Developmental and reproductive effects	not tested
Carcinogenicity	not tested

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical (Batch 94-0077)
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/CD(SD)BR VAF/Plus Charles River
Vehicle	Administered as 20% suspension in 0.5% aqueous suspension of guar gum.
Remarks - Method	Gavage

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity	Discoloured (green) faeces noted in all animals on the day after dosing. No other abnormal clinical signs were noted, and all animals gained weight during the 14-day observation period.
Effects in Organs	No treatment related changes were found at necroscopy.
Remarks - Results	Histopathological examination of tissues was not carried out.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Eastman Kodak (1997a)

7.2. Acute toxicity - dermal

TEST SUBSTANCE	Notified chemical (Batch 94-0077)
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/CD(SD)BR VAF/Plus Charles River
Vehicle	Administered as a solid, moistened with water
Type of dressing	Occlusive over fibre pad.
Remarks - Method	After 24 h, any residual material was removed from the skin with acetone and running water.

RESULTS

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

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	The test material stained the skin and hair yellow at the site of application.
Signs of Toxicity - Systemic	None
Effects in Organs	The only treatment-related change noted at necroscopy was stained yellow hair in most animals at the site of application.
Remarks - Results	Histopathological examination of tissues was not carried out.

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

TEST FACILITY Eastman Kodak (1997b)

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical (Batch 94-0077)

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

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Administered as a solid, moistened with water.
Observation Period	72 h
Type of Dressing	Occlusive over fibre pad.
Remarks - Method	Dose 0.5 g. After the exposure period of 4 h, any residual material was removed from the skin with acetone and 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 The test material caused very slight to slight yellow staining at the application sites of all animals. The staining did not hinder observations for erythema.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY Eastman Kodak (1997c)

7.5 Irritation - eye

7.5.1. Eye irritation in vivo

TEST SUBSTANCE Notified chemical (Batch 94-0077)

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	3
Observation Period	72 h
Remarks - Method	Dose was 0.1 g of the notified chemical, a yellow powder. The pH was 5.6 (concentration not stated), confirming that the chemical is neither strongly acid or alkaline. The chemical was not washed from the eyes of the test animals. An additional 3 animals were treated, except that their eyes were immediately washed with running distilled water. At 24 h after dosing, the eyes were treated with a 2% ophthalmic solution of fluorescein and observed for staining.

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	0.33	0	0.33	2	24 h	0
Conjunctiva: chemosis	0	0	0	-	-	-
Corneal opacity	0	0	0	-	-	-
Iridial inflammation	0	0	0	-	-	-

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

Remarks - Results	Slight to moderate erythema was observed in unwashed eyes (see table above), and was slightly less severe when eyes were washed immediately after dosing. No corneal opacity, iris effects or chemosis was noted in either group. Slight (2 animals) and moderate (1 animal) discharge was noted 1 h after dosing in unwashed group and slight discharge (1 animal) in the washed group. No staining was evident in washed or unwashed eyes when tested at 24 h with fluorescein.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Eastman Kodak (1997f)

7.5.2 Eye irritation in vitro – EYTEX Bioassay

TEST SUBSTANCE	Notified chemical (Batch 94-0077)
METHOD	EYTEX Bioassay, an in vitro ocular irritation test
Remarks - Method	The assay reagent is a synthetic 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 irritancy is calculated from a calibration curve of irritants with known in vivo Draize results As the pH of the notified chemical (10% solution) was 3.9, the Eytex Upright Membrane Assay (UMA) protocol was used. This protocol is used for samples of pH <8. 20 mg, 30 mg, 40 mg, 50 mg and 100 mg samples of the notified chemical were tested

RESULTS

Sample amounts	EYTEX Draize equivalents	Projected irritant class*
20 mg	1.3	Minimal

30 mg	3.6	Minimal
40 mg	3.5	Minimal
50 mg	5.7	Minimal
100 mg	14.1	Minimal

* EYTEX Draize equivalents of 0.0 to 15.0 are classed as minimally irritant

CONCLUSION Test results suggest that the notified chemical has the potential to produce minimal eye irritation.

TEST FACILITY Eastman Kodak (1997d)

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical (Batch 94-0077)

METHOD OECD TG 406 Skin Sensitisation – Guinea Pig Maximisation Test.
Species/Strain Guinea pig/Crl:(HA)BR VAF/Plus Charles River
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 5% (the only concentration tested)
topical: 25% (the only concentration tested)
MAIN STUDY
Number of Animals Test Group: 20 Control Group: 10
INDUCTION PHASE Induction Concentration:
intradermal: 5%
topical: 25%
Signs of Irritation None
CHALLENGE PHASE
1st challenge topical: 25%
Remarks - Method Topical applications were made with petrolatum as vehicle. Intradermal injections were carried out in corn oil or in FCA emulsion.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	25%	0	0	-	-
Control Group	25%	0	0	-	-

Remarks - Results A sensitisation study carried out on the same strain of guinea pigs with the known sensitiser 2-mercaptobenzothiazole produced positive sensitisation responses.

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 (1997e)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical (Batch 94-0077)

METHOD Analogous to OECD TG 471 Bacterial Reverse Mutation Test.
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*: WP2uvrA (pKM101).
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 25, 100, 500, 1000, 2500, 5000 µg/plate. b) Without metabolic activation: 25, 100, 500, 1000, 2500, 5000 µg/plate.
Vehicle	Deionised water
Remarks - Method	Test article formed an opaque suspension in deionised water at 100mg/mL (5000 µg/plate). It formed a solution at 1 mg/mL (100 µg/plate) and the test report states that it remained a solution at all subsequent doses prepared for the mutagenicity assay. However it is not stated whether the test article preparations used at intermediate doses was in solution or suspension.

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	> 5000 µg/plate	Heavy precipitate at > 1000 µg/plate	Negative
Present				
Test 1	> 5000 µg/plate	> 5000 µg/plate	Heavy precipitate at > 1000 µg/plate	Negative

Remarks - Results	The low solubility of the notified chemical in deionised water at some of the test concentrations may have affected the availability of the chemical to the bacteria. However, there was no indication that the number of revertants increased at any dose, in the presence or absence of metabolic activation, and no sign of dose-response relationship was evident.
CONCLUSION	The notified chemical is not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Hazelton (1994)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO2 Evolution Test (modified Sturm test)
Inoculum	Supernatant from homogenised (blended) and settled activated sludge mixed liquor from a sewage treatment plant receiving mostly domestic wastewater (Van Lare Treatment Plant).
Exposure Period	28 d
Auxiliary Solvent	None
Analytical Monitoring	Titration
Remarks - Method	Five test containers (3 L carboys; 2 X test material; 1 X positive control; 2 X Inoculum Blank) contained ~1% inoculum. The initial test material concentration was 30 mg/L (20 mg DOC/L). Due to low water solubility, the test material was added directly to carboys with 500 mL of purged BSM. Microbial activity was checked using a positive control (Sodium benzoate 102.9 mg/500 mL purged Basal Salts Medium). To assess biodegradability, measured CO2 evolution was compared to theoretical CO2 (ThCO2) evolution. CO2 absorber bottles were collected periodically during the test for analysis.

RESULTS

Test substance(1st replicate)		*Sodium benzoate*	
Day	*% degradation*	*Day*	*% degradation*
1		1	10
6	0	6	52
14	5	14	70
20	5	20	74
24	6	24	76
28	6	28	77

Remarks - Results	There was a lag phase of 9 days before degradation of the test material achieved 10% in 10 days, but in only one of the 2 replicates tested. The positive control achieved >60% degradation by Day 14. The Inoculum Blanks (containing no test material) at the end of the test did not exceed 40 mg/L of medium, thereby validating the (acceptable).
CONCLUSION	The test material achieved only 6-17% biodegradation within 28 days. Not readily biodegradable under the test conditions.
TEST FACILITY	Eastman Kodak (1994g)

8.1.2. Bioaccumulation

TEST SUBSTANCE	Not determined. With a Log P_{ow} of 2.0, the notified chemical is slightly hydrophobic with only a moderate potential to bioaccumulate in exposed organisms and has limited aquatic exposure.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

With only a very slight volatility (vapour pressure <7.6 x 10^{-8} kPa at 25°C and estimated Henry's Law Constant of 1.3 x 10^{-5} Pa m^3/mole), volatilisation to the atmosphere is not likely to be a significant migration pathway. The notified chemical is readily soluble in water (4.1 g/L) and has a low affinity to organic carbon (log Koc of <1.25) and is expected to partition mostly in the aqueous phase in aquatic environments. Although it is not readily biodegradable under 28 day OECD test conditions, biotic and abiotic (hydrolysis) degradation of the notified chemical is expected to occur over time. Release of the notified chemical to the aquatic environment is unlikely under the proposed use and disposal pattern and no predicted environmental concentration (PEC) in the aqueous compartment can be determined.

9.1.2. Environment – effects assessment

No ecotoxicological data were available for the notified chemical.

9.1.3. Environment – risk characterisation

The majority of the notified chemical will be applied to paper articles and will be bound and coated with an overcoat where it is unlikely to be released to the environment. These articles will eventually be sent to landfill for disposal, where the notified chemical will eventually degrade through slow biological and abiotic processes. A fraction of the notified chemical may also be disposed of to landfill with emptied container residues. Within a landfill environment, he notified chemical is unlikely to pose an unacceptable risk to the environment. A fraction of the notified chemical may enter the wastewater, which will be treated on-site at an industrial wastewater treatment plant with most bound in filtercake (which is destroyed by combustion), prior to further treatment and dilution off-site within the municipal sewerage system. Although no ecotoxicological results for the notified chemical were available, the trace of notified chemical that may potentially enter the sewerage system, and diluted to a likely concentration of <10^{-4} μg/L, is unlikely to pose an unacceptable risk to the environment. Attenuation within the sewerage system is expected to further reduce this risk.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Workers will be potentially exposed to the notified chemical during the formulation and application of a coating for photographic paper.

The highest potential for exposure during the process occurs in the initial steps when the chemical is in powder form, as inhalation/ingestion exposure as well as dermal/ocular exposure is possible. However the potential for inhalation exposure is reduced because the powder is weighed under exhaust ventilation, and its particle size is relatively large, with only 0.24% in the inspirable range (< 100 μm) and none in the respirable range (< 10 μm). It is also expected that respiratory protection would be worn during the weighing step.

Dermal and ocular exposure to workers can potentially occur at all stages of the formulation process. Exposure could occur through spillage, splashing and cleaning processes but would be limited in the latter stages of formulation by the low concentration of the notified chemical (< 1%) and the automated processes used in these steps. Throughout the formulation process appropriate PPE are also worn to reduce exposure.

Dermal and ocular exposure can similarly occur during the paper coating process. As this is an automated process, exposure is most likely to occur only during adjustments or repairs to the machines. Exposure would also be minimised by the low concentration of the notified chemical in the coating mixture and the PPE worn during operations where contact is possible.

Exposure should not occur after the notified chemical is incorporated in the paper coating, as it is covered by other layers and is not available. Therefore no significant exposure is expected to workers who handle finished photographic paper.

9.2.2. Public health – exposure assessment

The possibility of public contact with the notified chemical before it is incorporated in photographic paper (eg as a result of a transport accident) is considered very low.
While the notified chemical is a component of the coating of photographic paper, it is bound to the substrate and covered by other coating layers and it is considered that exposure to the public through photographic paper would also be very low.

9.2.3. Human health - effects assessment

The notified chemical was of low acute oral and dermal toxicity when tested in rats. It was not a skin irritant in rabbits, but demonstrated slight eye irritation in rabbits and the potential for minimal eye irritation when tested in an in vitro system. Yellow staining was noted in the skin irritation study but did not occur in the in vivo eye irritation study. The notified chemical was not a skin sensitiser in a guinea pig maximisation test. It did not induce mutations in bacteria in the presence and absence of metabolic activation, however it was not soluble at high concentrations in the solvent used in this test.
No test reports were submitted for other genotoxicity tests, acute inhalation exposure, repeated dose toxicity, developmental and reproductive effects, carcinogenicity or toxicokinetics.

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 emulsion formulation, which forms one of several layers applied to photographic paper. In the initial stages of emulsion manufacture, there is the potential for inhalation or ingestion exposure to the notified chemical, as well as dermal and ocular exposure. Therefore there is a risk of skin and eye irritation during these processes. Airborne exposure will be reduced by the relatively large particle size of the chemical as imported.

In the later stages of emulsion manufacture and in the automated coating process, there is the potential for incidental dermal and ocular exposure, however the concentration of the notified chemical is low (<1%). It is expected that the planned engineering and PPE controls will reduce the extent of any exposure. Therefore there is little risk because exposure is low.

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. Therefore the risk of irritant effects is negligible.

Based on the toxicological data available, the overall health risk to workers is low, taking into account the high level of automation and engineering controls in place during the formulation and coating processes. However, as repeated dose toxicity data and full genotoxicity data were not available, exposure should be minimised where possible, particularly where direct handling of the notified chemical may occur e.g. during initial weighing and transfer of the chemical in the formulation.

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.

Based on the available data the notified chemical is not classified under the GHS on the basis of human health effects. Based on the data currently available, it is not possible to categorise the notified chemical for the environment according to the GHS.

10.2. Environmental risk assessment

The 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 in the proposed manner.

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, 1994a). 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, 1994b). 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 emulsion 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 emulsion 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 emulsion 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.

Disposal

- Dispose of wastes containing the notified chemical according to local jurisdiction waste disposal regulations. 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 collected 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 Subsection 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical.

or

(2) Under Subsection 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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