File No: SN/1

Date: 15 March 1993

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

SECONDARY NOTIFICATION OF C-1824

This Assessment has been compiled in accordance with the provisions of the Industrial Chemicals (Notification and Assessment) Act 1989 and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Arts. Sport, the Environment and Territories and the assessment of public health is conducted by the Department of Health, Housing and Community Services.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia 92-94 Parramatta Road. Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

For Enquiries please contact Ms Karen Bell at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050 AUSTRALIA Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA Telephone: (61) (02) 565-9466 FAX (61) (02) 565-9465

Director Chemicals Notification and Assessment

FULL PUBLIC REPORT

SECONDARY NOTIFICATION OF C-1824

INTRODUCTION

This report represents the revised assessment for C-1824 when introduced in quantities > 1 tonne/year.

Assessment of C-1824 was carried out under the Industrial Chemicals (Notification and Assessment) Act, 1989 and the Summary Report of that assessment was published in the Chemical Gazette No. C 5 dated 5 May 1992.

The initial notification estimated the projected import volume as less than one tonne/year for the first five years and, under the Act, data on toxicology and ecotoxicology testing were not required. However, some testing had been carried out and reports of these tests submitted and reviewed. The assessment report stipulated that if the volume of import/manufacture exceeded one tonne/year, additional data relating to environmental effects should be submitted.

The attached report incorporates the revised environmental assessment of C-1824 in the light of the newly submitted information.

The original review of occupational and public health was conducted on the information which would have been required to assess a chemical to be introduced in quantities greater than one tonne/year. Modification of the original report has not been required. Accordingly the sections of this report relating to toxicology, occupational and public health and the relevant recommendations are unchanged from the report dated 20 March 1992.

1. <u>APPLICANT</u>

Kodak Australasia Pty. Ltd., 173 Elizabeth Street, Coburg, Victoria, 3058.

2. IDENTITY OF CHEMICAL

Other name: C-1824

Molecular weight: 698.4

Based on the data submitted and the character of the chemical C-1824 is not expected to be a hazardous chemical. For this reason, its chemical name, molecular formula, structural formula and spectral data have been exempted from publication.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: white powder

Melting Point: 73.5°C

Density: $1.177 \times 10^3 \text{ kg/m3}$ @ 23°C (Air comparison

pycnometer)

Vapour pressure: $<1.3 \times 10^{-7} \text{ kPa } (a) < 64^{\circ}\text{C (V.P. balance method)}$

Water solubility: 2.8 ppb (calculated)

Hydrolysis as Function of pH: not able to test due to insolubility

n-Octanol/Water $\log \text{Kow} = 7.0$ **Partition Coefficient:** (OECD TG 117)

Adsorption/Desorption: not determined due to low solubility

Dissociation Constant: not determined

Fat Solubility at 37°C: $11000 \pm 350 \text{ mg}/100 \text{ g fat}$

Flash point: not provided as the chemical has negligible vapour

pressure

Flammability: combustible

Combustion products: carbon dioxide, carbon monoxide, HCl, and oxides of

nitrogen

Autoignition temperature: not autoignitable as the chemical has negligible vapour

pressure

Explosive properties: capable of dust explosion

Decomposition temperature: 390 °C

Decomposition products: methane, hydrogen chloride and oxides of carbon

Reactivity: oxidising; incompatible with strong oxidisers,

combustible materials and reducing agents.

Particle size: 8.68 x 10² micrometer (mean)

The initial water solubility value submitted by the notifier was < 0.5 mg/L the detection limit of the analytical method used (OECD TG 105). CEPA indicated that a water solubility of this level may still be environmentally significant and that the limit value precludes an accurate assessment of the chemical's fate in the water compartment. CEPA suggested this situation could be rectified through the use of a more sensitive HPLC detection limit or use of the HPLC method in OECD Test Guideline 117 to determine log K which in turn would allow calculation of a more accurate water solubility. Kodak responded by providing an estimated value of the partition coefficient according to the procedures outlined in OECD Test Guideline 117. From this value, Kodak calculated the water solubility using the equation:

log(1/S) = 1.339 logKow - 0.978; where S is in moles/L (1).

Hydrolysis was tested according to OECD Test Guideline 111 at three pH levels (4, 7 and 9), with acetonitrile as co-solvent. Insolubility of the test material again precluded a definitive result. A similar situation is likely to occur under environmental conditions and thus hydrolysis in the field is unlikely and no further testing should be required.

An adsorption desorption was also not performed due to the insolubility of the test material. The high log K is indicative of strong adsorption (1).

The substance contains no acidic or basic groups. Therefore the lack of a result for dissociation constant is acceptable.

4. PURITY OF THE CHEMICAL

Degree of purity: 99.5% w/w

Impurities: unknown (0.5% w/w)

Additives/Adjuvants: none

5. <u>INDUSTRIAL USE</u>

C-1824 will be imported for use in the manufacture of photographic film or paper. It will be present as a minor component in a dispersion. After importation, the notified chemical will be reformulated into a dispersion before being incorporated into the film or paper. During the next five years, C-1824 will be imported in quantities of 5-10 tonnes/year.

6. OCCUPATIONAL EXPOSURE

6.1 Reformulation process description

The notified chemical will be reformulated into a gelatin dispersion at only one site in Australia. It is stated in the notification that the notified chemical will be imported as preweighed units therefore routine re-weighing in Australia will not be necessary. The preweighed chemical in the form of a dry powder and other ingredients as determined by the formulation, will be added to mix tanks approximately 25 times a year. The addition of the notified chemical will take approximately 15 minutes each time. Mixing will be conducted under local exhaust ventilation. After mixing, the resulting dispersion will be chilled and then stored in closed plastic bags for up to several weeks. During use, the dispersion will be taken out of the bag and added to melt tanks, where other ingredients will be added. The resulting solution will then be pumped to controlled automatic processing equipment where the notified chemical will be incorporated into the film or paper.

6.2 Occupational Exposure

As the notified chemical will be imported and stored in sealed shipping containers, significant risk of worker exposure during transport and storage is unlikely. After reformulation, the notified chemical in a dispersion, will be stored in closed plastic bags in chilled storage areas.

Significant risk of exposure to the notified chemical in the dispersion during storage is not anticipated even in the event of an accidental spillage as it will be present at a very low level in the dispersion.

Potential exposure to the notified chemical will be during its handling and use. Operators involved with the mixing, packing, melting, equipment cleaning, and use of the dispersion, may come into direct contact with the notified chemical if engineering controls and personal protection measures are not implemented. The major route of direct contact with the notified chemical will be through the skin. C-1824 has a molecular weight of <1000 and a partition coefficient of >3.2 at 25°C, as a result, it has the potential to be absorbed through biological membranes such as the skin. As C-1824 is virtually insoluble in water and has a high melting point, very low vapour pressure, and particle size above the inspirable range (>185 µm). exposure through inhalation is likely to be minimal. Exposure to the notified chemical after reformulation will be very low due to its low level in the dispersion. It is stated in the notification that once the notified chemical becomes incorporated in the film or paper, no exposure is likely as the chemical will be protected by layers of overcoating. Therefore, it is anticipated that exposure of handlers and users of the treated film or paper to the notified chemical, will be negligible.

7. PUBLIC EXPOSURE

C-1824 will be imported in sealed shipping containers therefore public exposure to this chemical during transport is unlikely.

Under correct usage, public exposure to the notified chemical will be minimal due to minimal release of the chemical into the environment as the notifier states that it will be totally consumed in the manufacture of the dispersion and once incorporated into the film or paper, it will be coated by layers of overcoatings. According to the notifier, approximately 10% of the dispersion containing the notified chemical could be released to the municipal sewer, with an additional 10% released from automated processing equipment. However, public exposure will be minimised by secondary treatment of the municipal sewer at a facility operated by the Melbourne and Metropolitan Board of Works. In addition, <1% of waste may be sent to a secured landfill but although the notified chemical is fat soluble and is not readily biodegradable, bioaccumulation will be low due to its low level in the dispersion.

When the photographic film or paper is used, public exposure to the notified chemical will be negligible because it will be present as a minor component in the film or paper, and according to the notifier, once the dispersion is incorporated in the film or paper it will be coated by layers of overcoatings.

8. <u>ENVIRONMENTAL EXPOSURE</u>

The notifier has indicated the proposed usage of C-1824 for the next five years is increased from the previous estimate of less than one tonne/year to 5-10 tonnes/year:

Use

Manufacture or reformulation of the chemical will not occur in Australia. Therefore, there will not be any environmental release of the chemical via this route.

C-1824, in the form of a dispersion, is a minor component in the manufacture of film and paper within the importer's factory.

Environmental release

During use approximately 10% of the chemical reaches the sewer from the dispersion preparation area. This waste is expected to reduce, due to process improvements, to 9% in 1994 and 8% in 1995, 1996 and 1997. The municipal sewer flow is routed for secondary treatment at the Werribee treatment facility. Less than 1% of wastes may be sent to a secure landfill.

Another 9% is lost in waste when the dispersion is used in production. This is expected to reduce to 7.5% in 1994. 1995, 1996 and 1997 as processes are improved. In the limited notification (NA/35) the notifier stated that this waste also went to the sewer. However, tests done since the limited notification was made show that this waste does not reach the sewer, but is contained in the silver-bearing sludge produced by the Silver Recovery Department and is trapped in the filter cake produced by the recovery process. The chemical thus trapped is destroyed when the filter cake is smelted at Port Kembla to produce silver in the pure form. In the dispersion preparation area up to 0.65 tonne of C-1824 may be discharged to the Werribee Sewage Treatment plant per annum. The dispersion is made in groups of 6 batches with each group taking one day to produce. In 1993, 36 groups will be produced. This will increase to 43 groups in 1997.

Fate

C-1824 will mainly enter the environment when the dispersion containing the notified substance is discharged to the sewer. It would appear unlikely that C-1824 would undergo significant microbial or chemical breakdown in the sewerage system. Three treatment systems are combined throughout the course of a year at the Werribee treatment complex, land filtration in summer and grass filtration and lagoon treatment in winter (3). Its most likely fate would appear to be sorption onto suspended solids and settling out over the land or into lagoon sludge, as sewage inflow passes through the filtration systems at Werribee. This may result in the accumulation of C-1824 in the soil, but prospects of leaching to any appreciable extent appear minimal, in view of the low water solubility and expected strong adsorption.

Biodegradation

Results of ready biodegradability tests conducted according to the OECD Guideline 301B (2% and 4% degradation at 10 and 20 mg/L concentrations respectively) indicate that the chemical is not likely to be biodegraded in the sewerage system and will enter waterways unchanged. However due to its insolubility it is likely to partition onto sediment/sludge, or onto suspended solids. Thus the actual amount entering receiving waters is likely to be low compared with that entering the sewer. Sludge is likely to be spread on land at Werribee.

Bioaccumulation

As C-1824 has a low water solubility and is not likely to be readily biodegraded, it may bioaccumulate. A characteristic of organic chemicals which exhibit bioaccumulation is a molecular weight >100 giving a maximum capacity at about 350, then declining to a low capacity about 600 (4). C-1824's molecular weight of 698 and its complex functionality

indicates it has a low capacity to bioaccumulate (4). Further, as the log Pow value has been estimated as 7.0, these considerations taken together would indicate that C-1824's bioaccumulation potential is likely to be low.

The possibility of soil accumulation needs consideration. However, C-1810 contains linkages which would be expected to be vulnerable to microbial cleavage in the soil. Thus significant accumulation is not expected.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of C-1824

Test	Species	Outcome	Reference
Oral	rat	LD50: >2000 mg/kg	5
Dermal	rat	LD50: >2000 mg/kg	6
Skin irritation	rabbit	non-irritant	7
Eye irritation	rabbit	slight irritant	8
Skin sensitisation	guinea pig	non-sensitising	9

9.1.1 Oral toxicity (5)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 401 (10).

A single dose of 2000 mg/kg of C-1824 in a 0.5% aqueous solution of guar gum was administered by gavage to 10 *CD(SD)BR VAF/PLUS* rats (five males and five females). The animals were observed for 14 days. No deaths were noted during the study. Gain in bodyweight was unaffected. No abnormal clinical signs were noted. At necropsy, hydrometra of the uterus was observed in three females, and haemorrhage of the thymus was observed in one male. The latter effect is considered to be an incidental finding due to its low incidence of occurrence.

The results of this study indicate an acute oral LD₅₀ of >2000 mg/kg for C-1824 in male and female rats.

9.1.2 Dermal toxicity (6)

This study was carried out in accordance with the 0ECD Guidelines for Testing of Chemicals No: 402 (11).

A single dose of 2000 mg/kg of C-1824 moistened with water, was administered by occlusive application to the shaved backs of 10 (five males and five females) $CD(SD)BR\ VAF/PlusT$ rats for 24 hours. The animals were observed for 14 days. No deaths were noted during the study period. Gain in bodyweight was unaffected. No abnormal clinical signs were observed. At necropsy, unilateral hydronephrosis was observed in one male, and single cases of thymus

haemorrhage and hydrometra of the uterus were noted in the females. The former two effects are considered to be incidental findings due to their low incidence of occurrence; on the other hand, hydrometra of the uterus may be treatment related because it was found in 60% of cases in the acute oral toxicity study.

The results of this study indicate an acute dermal LD₅₀ of >2000 mg/kg for C-1824 in male and female rats.

9.1.3 Skin irritation (7)

This study was carried out in accordance with the 0ECD Guidelines for Testing of Chemicals No: 404 (12).

A single dose of 0.5 g of C-1824 moistened with water was administered by occlusive application to the clipped dorsal skin of three Hra:(NZW)SPF rabbits for four hours. The site of application was examined at 1, 24, 48 and 72 hours post exposure and thereafter at 7 and 14 days after the administration of the test substance. Effects were graded according to the numeric system described in the OECD Guideline No: 404 (12). No abnormal clinical signs or signs of irritation were observed during the study period. All animals survived the 14-day observation period and gain in bodyweight was unaffected. No necropsy was performed.

The results of this study indicate that C-1824 is a not a skin irritant in rabbits at the concentration tested.

9.1.4 Eye irritation (8)

This study was carried out in accordance with the 0ECD Guidelines for Testing of Chemicals No: 405 (13).

A single dose of 0.1 g of C-1824 was instilled into the conjunctival sac of one eye of each of six Hra:(NZW)SPF rabbits. Three of the eyes were immediately washed with running distilled water; the other three eyes were not irrigated. The untreated eye of each rabbit served as the control. The eyes were observed immediately after exposure and at 1. 24, 48 and 72 hours thereafter. Both eyes of each rabbit were tested with fluorescein dye and were examined for staining 24 hours after exposure. Effects were graded according to the numeric system described in the OECD Guideline No: 405 (13). Slight erythema of the conjunctivae and nictitating membranes were observed in all the washed and unwashed treated eyes. No corneal or adnexal staining was observed in any of the treated eyes or controls. One of the three unwashed treated eyes was normal 24 hours after exposure and the remaining two unwashed eyes were normal at 48 hours. The three washed treated eyes were normal 24 hours after exposure. No non-ocular effects were noted during the 72-hour period.

The results of this study indicate that C-1824 is a slight eye irritant in rabbits at the concentration tested.

9.1.5 Skin Sensitisation (9)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 406 (14).

The Buehler method (15, 16) was used. Effects were graded according to the numeric system described in (14). The sensitivity of the strain of guinea pigs to be used in this study was tested with a known skin sensitiser, 1-chloro-2,4-dinitrobenzene. Positive sensitisation responses were observed in the animals tested.

Preliminary study

A single dose of 0.5 g of C-1824 moistened with water (100% concentration) was administered by occlusive application to the shaved backs of three *Crl:(HA)BR VAF/PlusT* guinea pigs for six hours. The application site was examined 24 and 48 hours after exposure. No signs of irritation were seen in the animals tested. The minimal irritant concentration was not determined and the maximal non-irritant concentration was 100%.

Induction and Challenge study

20 Crl:(HA)BR VAF/PlusT guinea pigs (10 control and 10 induced animals - males and females) were used.

A 100% concentration of 0.5 g of C-1824 moistened with water was administered by occlusive application to the shaved backs of 10 guinea pigs for six hours. This procedure was repeated weekly for three weeks. Two weeks after the last induction procedure, the same 10 animals were challenged with the maximal non-irritant concentration of 100% but on the opposite side of the midline from the side used previously. The 10 control animals which were previously untreated were also subjected to the same challenge procedure. Effects were graded according to the numeric system described in (15). No signs of irritation or abnormal clinical signs were seen in any animal from both groups. Gain in bodyweight was unaffected. Animals were not necropsied at the conclusion of the study.

The results of this study indicate that C-1824 is not a skin sensitiser in guinea pigs at the concentration tested.

9.2 Repeated Dose Oral Toxicity (17)

This study was carried out in accordance with the OECD Guidelines for Testing of Chemicals No: 407 (18).

C-1824 in corn oil was administered by gavage once daily to groups of five male and five female CD(SD)BR rats at dose levels of 0, 100, 300 and 1000 mg/kg for a total of 22 doses over 30 days.

No deaths were noted during the study. Gain in bodyweight was unaffected. Alopecia was observed in one male animal from each of the low, intermediate and high dose groups and in one female from each of the intermediate and high dose groups. Single cases of dehydration, decreased faeces and neck wound were reported in males of the intermediate dose group; and diarrhoea and hair of iguinal region wetted by urine were observed in one female animal of the intermediate dose group. These clinical signs are considered to be not treatment related because of their low incidence of occurrence and the lack of a dose-response.

In both male and female rats, minimal abnormalities in red blood cells such as Howell-Jolly bodies, poikilocytosis and anisocytosis were observed at all dose levels in males and in the high dose group in females with anisocytosis also observed in the controls. These cellular abnormalities are considered to be not treatment related because of their low incidence of

occurence and the lack of a dose-response, and in the case of anisocytosis, the presence of such findings in the controls.

When compared with the controls, sorbitol dehydrogenase levels were decreased at all dose levels in male rats. However, the total bilirubin level was increased in high dose males. In females, alanine aminotransferase levels were increased and urea nitrogen levels were decreased in the high dose group. These effects are considered to be not indicative of toxicity due to the lack of concomitant changes in organ pathology or the direction of the response was not consistent with organ toxicity.

No significant differences were noted in mean organ weight or bodyweight between the controls and the treated animals.

At necropsy, gross findings in males showed single cases of calculus and mucosa thickening of the urinary bladder, and unilateral hydronephrosis. in males of the low dose group; in females, two cases of hydrometra were noted in the intermediate group and one case in the high-dose group. Thymus haemorrhage was seen in all groups including the control group. Histopathology showed in high-dose males, inflammation of the myocardium (1/5) and kidneys (1/5), hypertrophy of the thyroid glands (2/5), decreased thyroid colloid (2/5), and single cases of testicular and epididymides changes such as decreased spermatozoa, and spermatid and spermatocyte degeneration. In addition, hyperplasia of the urinary bladder mucosa (1/5) and inflammation of the thyroid gland (1/5) were seen in low and intermediate dose males respectively. In females, bilateral hydronephrosis (1/5 of high dose group) and hydrometra (2/5 of the high dose group and 2/2 of the intermediate dose group) were observed. All of the histopathology effects listed above were not seen in control animals. Hydrometra was also reported in 3/5 females administered 2000 mg/kg of C-1824 in the acute oral toxicity study (6) and in 1/5 females in the acute dermal toxicity study (7). It should be noted that the incidence of hydrometra could possibly be higher in the 28-day study as only two animals out of five from the intermediate dose group were examined for this effect and in both of these animals, a positive finding was noted. Although a dose-related effect cannot be established from the data accumulated, the number of cases reported with C-1824 suggest that hydrometra maybe treatment related. The notifier states that thyroid hypertrophy in high-dose males is treatment related as such an effect is infrequently seen as a spontaneous change. It is also stated in the notification that testicular and epididymides changes are considered to be not treatment related as they occur spontaneously in rats of the strain used in this study and also because of their low incidence of occurrence. The remaining histopathological effects reported above are considered to be not treatment related due to their low incidence of occurrence and the lack of a dose-response.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium reverse mutation assay (19)

This study was carried out in accordance with the 0ECD Guidelines for Testing of Chemicals No: 471 (20).

C-1824 at concentrations of 10000, 6670, 3330, 1000, 667 and 333 ug/plate was tested in two independent experiments for gene mutation according to the direct plate incorporation method (21) using *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538. both in the presence and absence of microsomal enzymes (S9 mix). Positive controls used were 2-aminoanthracene. 2-nitrofluorene, sodium azide and ICR-191. Dimethylformamide was used as the vehicle control. When compared to the vehicle control, in the presence or

absence of microsomal activation, C-1824 at the concentrations tested did not produce any statistically significant dose-response increase in the number of revertant colonies. On the other hand, the positive controls showed marked increases.

The results of this study suggest that C-1824 was non-mutagenic under the test conditions reported.

9.3.2 Micronucleus assay in the bone marrow cells of the mouse (22)

This study was carried.out in accordance with the 0ECD Guidelines for Testing of Chemicals.No: 474 (23).

C-1824 in corn oil was administered by gavage to groups of 20 Swiss *CD-1*, *Crl:CD-1* (*ICR)BR* mice (ten males and ten females) at dose levels of 0. 200, 1000 and 2000 mg/kg. The vehicle, corn oil, was used as negative control and cyclophosphamide was used as the positive control. Groups of ten animals (five males and five females) from each dose level were harvested at 24 or 48 hours after administration of the test substance or the vehicle. The positive control group which consisted of 10 animals (five males and five females), was harvested at 24 hours only. When compared to the negative control, no statistically significant increase in micronucleated polychromatic cells was observed in any of the animals treated with C-1824. In contrast, the positive control showed statistically significant increases at 24 hours in both male and female rats.

The results of this study suggest that C-1824 was not genotoxic under the test conditions reported.

9.4 Overall assessment of toxicological data

C-1824 has low acute oral and dermal toxicity (oral LD₅₀ in rats: >2000 mg/kg; dermal LD₅₀ in rats: >2000 mg/kg). Animal tests show that it is a slight eye irritant but not a skin sensitiser nor a skin irritant. A short-term repeated dose study shows incidences of hydrometra in female rats of the intermediate (300 mg/kg) and high-dose (1000 mg/kg) groups and thyroid hypertrophy in male rats of the high-dose group. Results from both the *Salmonella typhimurium* reverse mutation assay and the in-vivo mouse micronucleus assay suggest that C-1824 is not genotoxic.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following results were obtained in static tests using nominal concentrations.

Test	Species	Result	Reference
Acute toxicity	1 1	$96 \text{ h } LC_{50} > 31 \text{ mg/L}$ NOEC = 31 mg/L	24
Acute toxicity	Daphnia magna	$\begin{array}{lll} 48 & h & EC_{50} &=& 29 & mg/L \\ NOEC = 2.8 & mg/L \end{array}$	25

OECD Guidelines were followed - static conditions were used for fish (26), and static renewal for *Daphnia* (27).

Concentrations tested [(1.6 - 80 mg/L) for *Daphnia* (27) and (0.31 - 31 mg/L) for fathead minnows] all exceeded the aqueous solubility of the substance and undissolved material was observed throughout in all solutions.

The 96 h NOEC for *Daphnia* is stated to be conservative, a few test organisms exhibited adverse effects after being encumbered by undissolved test material at higher doses.

Thus while the actual concentration is unclear, the fish and *Daphnia* are not expected to suffer acute effects up to the limit of solubility (0.5 ppm) of the substance.

The company has stated it is not practical or feasible to perform the daphnid reproductive test as described in OECD TG 202 since the test article has extremely low aqueous solubility, cannot be analytically detected at any of the proposed exposure concentrations, and does not seem to exhibit appreciable intrinsic chemical toxicity to *Daphnia magna*.

CEPA notes that while reproduction tests for daphnids were not conducted, the apparent lack of acute toxicity and the probability that C-1824, given its relatively high molecular weight and complex functionality, will not be absorbed by living cells, indicate that reproductive effects are unlikely to be observed.

Algal tests were similarly not conducted, but significant exposure of algae is not expected given that the substance will be discharged to the Melbourne sewerage system and is expected to become associated with the soil compartment at Werribee.

An activated sludge respiratory inhibition test (28) using OECD Guideline 209 (29) was also conducted. Respiratory inhibition in microorganisms following 3 h exposure to acetone-solubilised substance was measured. A NOEC value of >100 mg/L (highest concentration tested) was observed. These results suggest that the substance should not affect sewerage treatment plants.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Up to 0.65 tonne of C-1824 may be discharged to the Werribee Sewerage Treatment plant per annum. As noted above, the dispersion will be made up 36 times in 1993, increasing to 43 times by 1997. Each dispersion requires 180 kg of C-1824 and, in a "worst case" situation, 10% of C-1824 used (ie 18 kg) is discharged to sewer. The following calculation using company estimates indicates the final concentration reached will be 7.2 ppb.

Quantity of C-1824 to sewer per day

Flow rate into Werribee

Concentration of C-1824 at Werribee

Rate of dilution in receiving waters

Final concentration = 18 kg 8 $= 5 \text{ x } 10^8 \text{ L/day}$ = 36 ppb = 5 - 25 times = 7.2 - 1.4 ppb

This calculation assumes there will be no losses due to adsorption to sediment etc. The concentration is the same order of magnitude as the calculated water solubility. While aquatic organisms were exposed to levels several orders of magnitude higher than this with no apparent effects, undissolved material was present and the real level of exposure is unclear. However the substance is likely to remain with the Werribee sewerage complex, adsorbed to

either sediment or soil, and the expected exposure to natural organisms is likely to be low. Therefore. C-1824 is likely to present a low hazard to the environment.

12. <u>ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS</u>

So far, no information on the effects of C-1824 on human health has been reported. Animal tests indicate that C-1824 is a slight eye irritant.

C-1824 is combustible and is capable of a dust explosion. However, good housekeeping and the implementation of control measures in the workplace such as adequate ventilation, the elimination of ignition sources, hot surfaces and high temperatures. and the earthing and dustproofing of all electrical fittings, machinery and equipment, will minimise the possibility of a dust explosion.

Under normal use conditions when control and precautionary measures are implemented, it is unlikely that the notified chemical will present any significant acute health or safety hazard to workers.

13. RECOMMNDATIONS

To minimise worker exposure and occupational hazard in the factory environment, the following guidelines and precautions should be observed:

- the workplace should be well ventilated and local exhaust ventilation should be employed, particularly for the collection of foreseeable escapes of dust; enclosed systems should be used;
- good work practices should be implemented to avoid the generation of a dust cloud, splashings or spillages;
- storage of the notified chemical and its dispersion should be in robust sealable containers. The powder form of the notified chemical should be stored in well ventilated places away from heat and sources of ignition;
- good housekeeping and maintenance should be practised especially to avoid the accumulation of dust in the workplace. Spillages should be cleaned up promptly and a vacuum cleaner should be used to pick up the powder so as to avoid the generation of a dust cloud;
- suitable personal protective equipment which comply with Australian standards (AS) should be worn such as:
 - safety glasses (AS 1337) (30);
 - protective gloves (AS 2161) (31);
 - protective clothing; and

- respirators (AS 1716) (32) in situations when ventilation is not available or insufficient.
- all sources of ignition, hot surfaces or high temperatures should be eliminated in areas
 where the powder form of the notified chemical will be handled. Electrical fittings,
 machinery and equipment should be earthed and dust-proof; personal hygiene should
 be observed.
- a copy of the Material Safety Data Sheet for the notified chemical should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet for C-1824 (Attachment 1) was provided in Worksafe Australia format (33). This MSDS was provided by Kodak Australasia Pty Ltd as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Kodak Australasia Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Industrial Chemicals (Notification and Assessment) Act 1989 (the Act), secondary notification of C-1824 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

- 1. Lyman. W.J., Reehl, W.F. and Rosenblatt, D.H., eds., *Handbook of Chemical Estimation Methods*, McGraw-Hill, New York, 1982.
- 2. Hobbs, S.J., (1988), Industry category document: The UK photographic industry, Department of the Environment, UK.
- 3. "Australian Sewage Profile", (1988), DASET internal report.
- 4. Connell D W, (1990), "Bioaccumulation of Xenobiotic Compounds", CRC Press, p56.
- 5. Eastman Kodak Company, USA, "Acute Oral Toxicity Study in the Rat". Data on file. Report No: TX-91-225, 1991.
- 6. Eastman Kodak Company, USA, "Acute Dermal Toxicity Study in the Rat". Data on file, Report No: TX-91-226, 1991.
- 7. Eastman Kodak Company, USA, "Acute Dermal Irritation Study in the Rabbit". Data on file. Report No: TX-91-228, 1991.
- 8. Eastman Kodak Company, USA, "Acute Eye Irritation Study in the Rabbit". Data on file, Report No: TX-91-230, 1991.
- 9. Eastman Kodak Company, USA, "Skin Sensitisation Study (Buehler Method) in the Guinea Pig". Data on file, Report No: TX-91-229, 1991.

- 10. OECD Guidelines for Testing of Chemicals, "Acute Oral Toxicity" No: 401, 1981.
- 11. OECD Guidelines for Testing of Chemicals, "Acute Dermal Toxicity" No: 402, 1987.
- 12. OECD Guidelines for Testing of Chemicals, "Acute Dermal Irritation/Corrosion" No: 404, 1981.
- 13. OECD Guidelines for Testing of Chemicals, "Acute Eye Irritation/Corrosion" No: 405, 1987.
- 14. OECD Guidelines for Testing of Chemicals, "Skin Sensitisation' No: 406, 1981.
- 15. Buehler, E.V., "Delayed contact hypersensitivity in the guinea pig", *Arch. Dermatol.*, vol. 91, 1965, pp 171-175.
- 16. Ritz, H.L. and Buehler, E.V., "Planning, conduct and interpretation of guinea pig sensitisation patch tests", in *Current Concepts in Cutaneous Toxicity*. Drill, V.A. and Lazar, D. eds., Academic Press, New York, 1980, pp 25-40.
- 17. Eastman Kodak Company, USA, "Four-week Oral Toxicity Study in the Rat". Data on file. Report No: TX-91-279, 1991.
- 18. OECD Guidelines for Testing of Chemicals, "Repeated Dose Oral Toxicity Rodent: 28-day or 14-day Study" No: 407, 1981.
- 19. Eastman Kodak Company, USA, "Mutagenicity Test on C-1824 in the *Salmonella*/Mammalian Microsome Reverse Mutation Assay (Ames Test) with Confirmatory Assay". Data on file, Report No: 14451-0-401R. 1991.
- 20. OECD Guidelines for Testing of Chemicals, "Genetic Toxicology: Salmonella typhimurium, Reverse Mutation Assay" No: 471, 1983.
- 21. Ames, B.N., McCann, J. and Yamasaki, E., "Methods for Detecting Carcinogens and Mutagens with the *Salmonella*/Mammalian-Microsome Mutagenicity Test", *Mutation Research*, vol.31, 1975, pp 347-364.
- 22. Eastman Kodak Company, USA, "*In-vivo* Mammalian Bone Marrow Mouse Micronucleus Assay". Data on file, Report No: TX-91-146, 1991.
- 23. OECD Guidelines for Testing of Chemicals, "Genetic Toxicology: Micronucleus Test" No: 474, 1983.
- 24. Eastman Kodak Company, USA, "Acute Aquatic Effects of C-1824 on Fathead Minnow, *Pimephales promelas*". Data on file, Report No: ES-91-026, 1991.
- 25. Eastman Kodak Company, USA, "Acute Aquatic Effects of C-1824 on the Daphnid, *Daphnia magna*". Data on file, Report No: ES-91-027, 1991.
- 26. OECD Guidelines for Testing of Chemicals, "Fish, Acute Toxicity Test" No: 203, 1981.
- 27. OECD Guidelines for Testing of Chemicals "Daphnia sp., 14-day Reproduction Test (including an Acute Immobilisation Test)" No: 202, 1981.

- 28. Eastman Kodak Company, USA, "Activated Sludge Respiration Inhibition Test". Data on file. Report No: ES-91-010, 1991.
- 29. OECD Guidelines for Testing of Chemicals. "Activated Sludge, Respiration Inhibition Test" No: 209, 1984.
- 30. Australian Standard 1337-1984. "Eye Protectors for Industrial Applications", Standards Association of Australia Publ., Sydney. 1984.
- 31. Australian Standard 2161-1978, "Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)", Standards Association of Australia Publ., Sydney, 1978.
- 32. Australian Standard 1716-1984, "Respiratory Protective Devices". Standards Association of Australia Publ., Sydney. 1984.
- 33. National Occupational Health and Safety Commission, *Guidance Note for the Completion of a Material Safety Data Sheet*, 2nd. edition, AGPS, Canberra, 1990.