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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

C-1862

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989, as amended* 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 Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health, Housing, Local Government and Community Services.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

C-1862

1. APPLICANT

Kodak Australasia Pty Ltd, 173 Elizabeth St, Coburg, Victoria

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, C-1862, is considered to be non-hazardous. Therefore, the chemical identity, molecular and structural formulae and specific use have been exempted from publication in the Full Public Report and the Summary Report.

Chemical name: C-1862

Chemical Abstracts Service

(CAS) Registry No.: Not available

Molecular weight: 1040.09

Method of detection and determination:

High Performance Liquid Chromatography with UV detection

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: white powder

Melting Point: 200.7°C

Density: 1208.8 kg/m³ at 23°C

Vapour Pressure: 1.6 X 10⁻⁹ kPa at 25°C

Water Solubility: 4.1 X 10⁻⁸ g/L (estimated)

Fat Solubility: 30.6 mg/ 100 g of fat at 37°C

Partition Co-efficient (n-octanol/water) log P_{O/W}:	8.5
Hydrolysis as a function of pH:	Approximate half-life of 3.02 X 10 ⁴ hours in pH 4 buffer and 264 hours in pH 7 buffer at 25°C. Hydrolysed < 10% at 50°C over 5 days in pH 9 buffer
Adsorption/Desorption:	Not performed due to low water solubility
Dissociation Constant:	The notified chemical was not soluble enough in water or in an organic solvent/ water mixture for determination of the pKa
Combustion Products:	Combustion will produce carbon dioxide and probably carbon monoxide. Hydrogen chloride gas and oxides of sulfur and nitrogen may also be present. The material is combustible but not flammable or pyrophoric
Explosive Properties:	No measurable explosive properties
Reactivity:	No measurable oxidising properties
Particle size distribution:	range - 38 - 2360 µm mean - 373 µm

Comments on the Physico-Chemical Properties

The notifier provided an estimated value of the partition coefficient according to procedures outlined in OECD Test Guideline 117. From this value, the notifier calculated the water solubility using the equation:

$$\log(1/S) = 1.339\log K_{OW} - 0.978; \text{ where } S \text{ is in moles/L (1).}$$

The adsorption-desorption test was not performed due to incompatibility of the test article with the 0.01M CaCl₂ matrix. Due to the high partition co-efficient strong adsorption to soils may be expected, though it is noted that fat solubility is also low.

No data were provided for the dissociation constant on the grounds that the test chemical is not soluble enough in water or in an organic solvent/water mixture for determination of the pKa by potentiometric titration. The substance has two non-amide nitrogens but their basicity is unclear.

4. PURITY OF THE CHEMICAL

Degree of purity: 96.1 - 97.0%

Toxic or hazardous impurities: None reported

Non-hazardous impurity: (> 1% by weight)

. **Chemical name:** Brominated C-1862
Weight percentage: 2.4%

Additives/Adjuvants: None

5. INDUSTRIAL USE

The notified chemical will be used in the manufacture of photographic film/paper. It will be imported in 5-6 kg preweighed units in polythene bags inside cardboard boxes.

The expected import volumes are: 400 kg in 1993, 2700 kg in 1994, 3200 kg in 1995 and 3500 kg in 1996.

6. OCCUPATIONAL EXPOSURE

The preweighed chemical will be added to mix tanks under local exhaust ventilation approximately 30 times per year in three-batch measures (90 batches per year). The addition of the dry chemical will take approximately 15 minutes per batch. The notified chemical is dissolved in solvents under heating and then

educted to another mix tank. Other ingredients will be added to this mix tank and the contents homogenised to a dispersion. The dispersion will be chilled and stored in 20 kg covered cans for up to several weeks. The dispersion will then be taken from storage and added to melt tanks, where other addenda will be added. The dispersion will then be pumped to closely controlled automated processing equipment where the notified chemical will be incorporated into articles.

The concentration of the notified chemical in the dispersion and in the melt (within the automated processing equipment) will be low.

Once the notified chemical is part of an article, it will be overcoated by additional layers.

7. PUBLIC EXPOSURE

There is low potential for public exposure to the notified chemical during distribution, formulation, application to articles and disposal. Once incorporated into articles public exposure to the notified chemical should be minimal as a result of it being under overcoat layers.

8. ENVIRONMENTAL EXPOSURE

. Release

The notifier states there are no anticipated releases to the environment of the pure chemical. Approximately 10 % of the aqueous dispersion containing C-1862 could be released to the municipal sewer. Any of the chemical released from the automated processing equipment (from the melt tank) is trapped by the silver recovery plant as "filter cake". Any chemical trapped in the filter cake would be expected to be destroyed when the filter cake is smelted at Port Kembla to regenerate silver.

The likely dilution factor for the new chemical released as an aqueous solution to the municipal sewer is approximately 1:10,000. The dilution factor of 1:10,000 refers to the sewer flow from the Kodak plant. The flow is approximately 400,000 L per day and mixes with the average daily inflow to the Werribee treatment plant of 500 megalitres.

. **Fate**

A batch of dispersion containing 30 kg of new chemical, with an expected waste of 10% would result in a 3 kg release to the sewer. This quantity will be diluted into 500 megalitres at Werribee, giving a concentration of approximately 0.6 ppb. There are no anticipated releases to the environment of the pure chemical.

Additionally, less than 1% of wastes may be sent to a secured landfill.

C-1862 will mainly enter the environment when the dispersion containing the notified substance is discharged to the sewer. It would appear unlikely that C-1862 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 (2). 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-1862 in the soil, but prospects of leaching to any appreciable extent appear minimal, in view of the extremely low water solubility and expected strong adsorption.

. Biodegradation (3)

Ready biodegradability was investigated using the modified Sturm test (OECD Guideline 301B) with measurement of evolved carbon dioxide. The extent of biodegradation amounted to 3% in 28 days at nominal concentration of 10 ppm and -3% (i.e. CO₂ evolution was less than the blank control) at 20 ppm. The results indicate that C-1862 is not readily biodegradable.

. Bioaccumulation

C-1862 is almost insoluble in water and is not readily biodegraded. Therefore, it may bioaccumulate. However, the high molecular weight and relatively large molecular size may preclude this (4). Further, as the log P_{ow} value has been estimated as 8.5, these considerations taken together would indicate that C-

1862's bioaccumulation potential is likely to be low. The molecule is also not very fat soluble.

The possibility of soil accumulation needs consideration. However, C-1862 contains linkages such as the amide 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-1862

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD ₅₀ > 2000 mg/kg	(5)
Acute dermal toxicity	Rat	LD ₅₀ > 2000 mg/kg	(6)
Skin irritation	Rabbit	Non-irritant	(7)
Eye irritation	Rabbit	Slight irritant	(8)
Skin sensitisation	Guinea Pig	Non-sensitiser	(9)

9.1.1 Oral Toxicity (Ref No:5)

A limit test was performed using a 20% formulation of the notified chemical in a 0.5% aqueous suspension of guar gum.

A single dose of the notified chemical at 2000 mg/kg was administered to 5 male and 5 female CD(SD)BR VAF/Plus rats by gavage. All animals were killed at the termination of the study after a 14 day observation period.

Abnormal clinical signs noted on the day of dosing were limited to discoloured (white) faeces in 2 of 5 animals of each sex.

No animals died during the study and no abnormalities were noted during gross necropsy examination.

It is concluded that the acute oral toxicity of the notified chemical is >2000 mg/kg.

9.1.2 Dermal Toxicity (Ref No:6)

A limit test was performed using pure C-1862 thoroughly moistened with water.

A single dose of the notified chemical at 2000 mg/kg was applied to the shaven dorsal skin of 5 male and 5 female CD(SD)BR VAF/PlusT rats using a fibre pad and an occlusive wrap to hold the test material in place. After 24 hours, the test material was washed off with running water.

No abnormal clinical signs were noted at any time during a 14 day observation period and all animals survived to necropsy. No treatment-related changes or signs of organ toxicity were noted at necropsy.

It is concluded that the acute dermal toxicity of the notified chemical is >2000 mg/kg.

9.1.3 Skin Irritation (Ref No:7)

The notified chemical, thoroughly moistened with water, was evaluated for potential as a primary skin irritant using 3 New Zealand white rabbits. Each rabbit was administered 0.5 g of the test article topically to one intact test site. Immediately following dose administration, each test site was covered with a fibre pad and an occlusive wrap. The patch was removed 4 hours after dose administration and the sites rinsed with running water.

No erythema or oedema was observed at 1 hour or 1, 2, 3, 7 or 14 days after removal of the occlusive patch.

The results indicate that the notified chemical is not an irritant to rabbit skin.

9.1.4 Eye Irritation (Ref No:8)

An eye irritation study was conducted with the notified chemical using 6 New Zealand white rabbits. After administration of a single dose of 0.1 gram of the notified chemical into the

conjunctival sac of one eye of each animal, three of the six treated eyes were washed with distilled water. The eyes of the remaining three animals were not irrigated.

No corneal opacity, iris effects or conjunctival oedema (chemosis) were observed in any animal at any time after treatment. For the unwashed eyes, at 1 hour post-treatment all rabbits exhibited slight conjunctival erythema. In one rabbit this was unchanged at 24 hours post-treatment while in the other 2 rabbits moderate conjunctival erythema was observed. At 48 hours post-treatment, 1 rabbit exhibited no erythema and 2 rabbits slight erythema. No erythema was observed in any rabbit at 72 hours post-treatment.

Rinsing of the eyes was palliative.

It is concluded that C-1862 is a slight irritant to rabbit eyes.

9.1.5 Skin Sensitisation (Ref No:9)

The Buehler method was used to assess the sensitisation potential of C-1862 in the Cr1:(HA)BR VAF/PlusT strain of guinea pigs.

The maximal non-irritant dose of 100% was determined prior to commencement of the study. In the induction phase, the backs of 10 guinea pigs were clipped prior to the application of one-half gram of C-1862, thoroughly moistened with water, under a fibre pad. The pads containing the notified chemical were held in place by wrapping an elastic adhesive bandage around the torso of the animal and securing it in place. After 6 hours, the patch was removed and the skin wiped free of excess test substance. This procedure was repeated weekly for 3 weeks.

The challenge dose was administered two weeks after the last induction exposure. The maximal non-irritant concentration, 100%, was applied to the backs of the 10 guinea pigs using the same procedure as for induction except that the patches with test material were applied to the backs on the opposite side of the midline to that used for the induction procedure. To differentiate dermal irritation from sensitisation, the remaining 10 previously untreated animals were subjected to the same challenge procedure. Evaluations of erythema and oedema were made on both groups of animals at 24 and 48 hours.

No signs of erythema or oedema were evident at the application site on any of the irritation control animals or animals in the induction and challenge groups.

It is concluded that C-1862 is not a skin sensitiser in guinea pigs.

9.2 Repeated Dose Toxicity (Ref No:10)

A 28-day oral toxicity study was conducted using a suspension of C-1862 in corn oil administered by gavage to Sprague-Dawley rats at dose levels of 100, 300 and 1000 mg/kg/day for 5 days per week. Control animals received vehicle (corn oil) at the same dose volume as administered to the treated animals. Groups of 5 male and 5 female rats were used for all doses. After 30 days on test, animals were anaesthetised, bled for clinical pathology, killed and necropsied.

No significant differences between the control and treatment groups were noted for body weight or feed consumption.

The test substance produced no overt toxicity.

Treatment-related clinical signs were limited to sialorrhoea in one 100 mg/kg/day male rat immediately after dosing, ascribed to the taste of C-1862.

Mean platelet counts in the 100 mg/kg/day male group were statistically ($P < 0.05$) lower than in the control group by 17%. Mean prothrombin times in the 100 and 1000 mg/kg/day male groups were statistically ($P < 0.05$) higher than in the control group by 0.4 and 0.6 seconds respectively. These changes were not considered to be biologically significant.

Minimal to minor poikilocytosis (a common variant in red blood cell morphology) was observed in the 300 and 1000 mg/kg/day male groups and in the 100 and 1000 mg/kg/day female groups. Because poikilocytosis is a common haematologic variant in rats and there was no difference in severity among groups, this finding is considered unlikely to be toxicologically significant.

Anisocytosis and microcytosis were observed in one 100 mg/kg/day female and this animal had a slightly lower haematocrit compared with other animals in that group. These effects were considered incidental.

An incidental observation was a substantially higher alkaline phosphatase activity in male of the 100 mg/kg/day group compared to levels in the control group.

No significant differences in relative organ weight were observed in male animals. Mean relative (to body weight) kidney weights of female rats in the 300 mg/kg/day dose group, and mean relative thymus weights of female rats in the 1000 mg/kg/day dose group were statistically ($P \leq 0.05$) lower than in the control group. These changes were not considered toxicologically significant because there was no correlation with the histopathology.

No treatment-related differences in gross or histopathology were observed.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Ref No:11)

C-1862 was assayed for induction of prototrophic back mutants in *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538 in the presence or absence of metabolic activation provided by rat liver S9.

Negative controls (dimethylsulfoxide as solvent) were within acceptable limits and positive controls (with metabolic activation - 2-aminoanthracene, all strains; without metabolic activation: 2-nitrofluorene for TA 98 and TA 1538; sodium azide for TA 100 and TA 1535; ICR-191 for TA 1537) gave the expected responses.

No induced mutants were observed at any dose level from 100 to 5000 µg of C-1862 per plate in either the presence or absence of metabolic activation.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Ref No:12)

The ability of C-1862 to induce micronuclei in bone marrow polychromatic erythrocytes (PCEs) of groups of Swiss CD-1 mice was assessed after oral administration by gavage. Dose groups consisted of 5 males and 5 females and doses used were 500, 1000 and 2000 mg/kg as suspensions in corn oil. Control animals received corn oil alone. Two harvest times of 24 and 48 hours

were used so that there were 2 control groups and 2 dose groups for each dose. A positive control group, dosed with cyclophosphamide at 80 mg/kg, was included only at the 24 hour harvest time.

C-1862 did not induce significant increases in micronucleated polychromatic erythrocytes (MNPCEs) in either male or female mice, at either the 24- or 48-hour harvest time when compared with concurrent negative controls. The numbers of normochromatic erythrocytes (NCEs) were counted along with the PCEs and C-1862 did not produce significant decreases in the number of PCEs relative to NCEs at either harvest time. By contrast, the positive control, cyclophosphamide, induced highly significant increases in MNPCEs and statistically significant decreases in the relative numbers of PCEs in both the male and female mice at 24 hours.

It is concluded that C-1862 is negative in the *in vivo* mouse bone marrow micronucleus assay.

9.3.3 Chromosomal Aberrations in Chinese Hamster Ovary Cells (13)

The ability of C-1862 to induce chromosomal aberrations in Chinese hamster ovary (CHO) cells was evaluated in the presence or absence of metabolic activation provided by rat liver S9.

Replicate cultures of CHO cells were incubated with 150, 375, 750, 1130 and 1500 µg/ml of C-1862. The cultures were harvested after 10 hours in the absence of metabolic activation and after 10 and 20 hours in its presence. Cell cycle arrest was provided by 0.1 µg/mL Colcemid added 2.75 hours (without S9) or 2.5 hours (with S9) prior to harvest. Positive controls were 1 µg/mL mitomycin C (-S9) or 25 µg/mL cyclophosphamide (+S9).

Negative and positive controls gave the expected results.

C-1862 did not induce chromosomal aberrations above background levels in either the presence or absence of metabolic activation.

9.4 Overall Assessment of Toxicological Data

The acute oral toxicity of C-1862 in rats is low as is the acute dermal toxicity. The results of a 28-day repeated dose study in rats provided no evidence of toxicity and isolated effects on

haematology, clinical chemistry and organ weights were judged not to be of toxicological significance.

C-1862 was not a skin irritant in rabbits but was a slight eye irritant. It was not a skin sensitiser in guinea pigs and was not genotoxic as judged by its inability to induce mutations in *Salmonella typhimurium*, micronuclei in mouse bone marrow polychromatic erythrocytes or chromosomal aberrations in Chinese hamster ovary cells.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

<u>Test</u>	<u>Species</u>	<u>Result</u>
Acute toxicity	Fathead minnow <i>Pimephales</i> <i>promelas</i>	96h LC ₅₀ > 3.0 mg.L ⁻¹ NOEC = 3.0 mg.L ⁻¹ (14)
Acute toxicity	Water flea <i>Daphnia magna</i>	48h EC ₅₀ > 20.5 mg.L ⁻¹ NOEC = 20.5 mg.L ⁻¹ (15)
Acute toxicity	Alga <i>Selenastrum</i> <i>capricornutum</i>	EC ₅₀ could not be determined NOEC = 4.7 mg.L ⁻¹ (16)
Inhibition of Microbial Respiration Activity	Activated sludge from a domestic waste water treatment plant	EC ₅₀ at 3 h > 1000mg.L ⁻¹ (17)

Reports were provided and these indicate the above tests were satisfactorily conducted according to OECD Guidelines.

The carrier solvent N, N-dimethylformamide (DMF), at 5 g of test material per 25 mL of DMF, was used to solubilise the test material in the fish and daphnid tests and 1 g of test material in 10 mL of DMF in the algal test. Concentrations tested (1.9, 3.4, 6.2, 11.0, & 20.0 mg.L⁻¹) for *P. promelas* and *D. magna* all exceeded the aqueous solubility of C-1862 and undissolved material was observed throughout in all solutions. Although the actual concentrations are unclear, fathead minnows and *Daphnia* are unlikely to suffer acute effects up to the limit of solubility of C-1862.

Test concentrations (0.625, 1.25, 2.50, 5.0, & 10.0 mg.L⁻¹) for the alga *S. capricornutum* also exceeded the test chemical's

solubility. Because no effects were observed at any concentration tested the EC₅₀ and NOEC values could not be determined. Therefore, the NOEC value for *S. capricornutum* is the highest concentration tested (4.7 mg.L⁻¹). Because this concentration is more than 40 times the reported aqueous solubility (<0.1 mg.L⁻¹), significant exposure of algae are not expected given the substance will be discharged to the Melbourne sewerage system and is expected to become associated with the soil compartment at Werribee.

The respiration rates of sludge micro-organisms for the test values (1000, 500, 100, 50, & 25 mg.L⁻¹), were 36.0, 34.11, 36.0, 36.0, & 36.80 mg.O₂.L⁻¹.h⁻¹ respectively, and were not significantly different from the controls. Therefore, the 3 hour respiration inhibition test resulted in an EC₅₀ value of > 1000 mg.L⁻¹. Owing to its almost insolubility in water, the test material was added as a particulate directly to the test medium.

The above results indicate that C-1862 is practically non-toxic to aquatic fauna up to the limit of its solubility and will not interfere with the necessary aerobic microbial action in sewage sludge. While reproduction tests for daphnids were not conducted, the apparent lack of acute toxicity and the probability the notified chemical, 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.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Up to 0.70 tonne of C-1862 may be discharged to sewage treatment works per annum where it is likely to adsorb to sludge or soil. It should be noted that the chemical is a replacement for one of 6 chemicals of this type (with similar physico-chemical properties) used during the one product run, resulting in the notifier releasing approximately 3.6 tonne of the chemicals per annum to the sewer. This is a worse case assuming 20% is discharged to the sewer.

As noted previously, the dispersion is made up about 30 times per year and assuming equal lots, about 20 kg per batch is discharged. A "worst case" calculation, using the notifier's estimates, indicates the final concentration reached will be 0.6 ppb. This calculation assumes there will be no losses due to

adsorption to sediment etc. The concentration is still several orders of magnitude higher than the calculated water solubility for C-1862. While aquatic organisms were exposed to levels several orders of magnitude higher than this with no apparent chemical effects, this was largely due to undissolved material and the real level of exposure is unclear. However, the substance is likely to remain with the Werribee sewerage complex, adsorbed to or associated with either sediments or soil, and the expected exposure to natural organisms and bioaccumulation is likely to be low. Therefore, C-1862 is likely to present a low hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The only health effect of significance is likely to be slight eye irritation as a result of mechanical injury by the dry C-1862 in particulate form. As addition of the notified chemical to the mix tank is in small amounts under local exhaust ventilation for a limited time per batch, for a relatively low number of batches per year, the probability of eye irritation occurring in the workplace as a result of contact with the powder is expected to be low.

Due to the low potential for public exposure, there should be minimal risk to public safety.

13. RECOMMENDATIONS

To minimise occupational exposure (and public/environmental if recommendations have been made by these agencies) to C-1862 the following guidelines and precautions should be observed:

- . if engineering controls and work practices are insufficient to reduce exposure to C-1862 to a safe level, then personal protective devices which conform to and are used in accordance with Australian Standards (AS) for eye protection (AS 1336; AS 1337) (18,19), impermeable gloves (AS 2161) (20) and protective clothing (AS 3765.1, 3765.2) (21,22) should be worn;
- . precautions should be taken to minimise the generation of dust. Good exhaust ventilation should be employed to

maintain the level of dust at or below that recommended for nuisance dusts 10 mg/m³ (23);

- . good housekeeping and maintenance should be practised. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal in accordance with local or State regulations;
- . the workplace should be well ventilated;
- . good personal hygiene should be observed;
- . a copy of the Material Safety Data Sheet should be easily accessible to employees; and
- . the notifier should continue to pursue methods of reducing the quantity of these chemicals being discharged to the environment.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for C-1862 (Attachment 1) was provided in Worksafe Australia format (Ref No:24). 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*, as amended (the Act), secondary notification of C-1862 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

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