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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

C-1810

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

C-1810

1. APPLICANT

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

2. IDENTITY OF THE CHEMICAL

Based on the data provided, C-1810 is considered to be non-hazardous. Therefore, its chemical name, other names, CAS no., molecular formula, structural formula and specific use have been granted exemption from publication in the Full Public Report and Summary Report.

Molecular weight: 748.3 g/mole

Method of detection and determination: HPLC method supplied

Spectral data:

Ultra violet-visible, infrared, ^{1}H-nuclear magnetic resonance ^{13}C-nuclear magnetic resonance spectra were provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: White solid

Melting Point: 83.0-86.0°C

Particle Size: 312 µm (mean), 38 µm (minimum)

Specific Gravity/Density: 1,230 kg/m^3

Vapour Pressure: 4.20×10^{-8} kPa at 25°C (Balance method)

Water Solubility: 35 ppb (calculated)

Fat Solubility:	1842 mg/100 g of fat at 37°C
Partition Co-efficient: (n-octanol/water)	log Kow = 6.2
Hydrolysis as a function of pH:	Not determined as a result of low solubility in water.
Adsorption/Desorption:	Not determined
Dissociation Constant:	Not determined
Flash Point:	Not applicable to solids
Flammability Limits:	Combustible but not highly flammable or pyrophoric.
Pyrolysis products:	methane, ammonia, oxides of carbon, oxides of nitrogen and HCl gas.
Autoignition Temperature:	>400°C
Explosive Properties:	Powder is non-explosive. Dust capable of explosion.
Reactivity/Stability:	Not an oxidising agent. Incompatible with strong oxidising agents.

Comments on physical and chemical parameters

The partition coefficient was estimated using a HPLC procedure outlined in OECD Test Guideline 117. From this value, the water solubility using the equation:

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

was calculated (1).

The adsorption-desorption test was not conducted as the notifier was unable to measure the test substance in aqueous solution with sufficient sensitivity. However, the notifier indicated that the notified substance was observed to adhere to surfaces in vessels in which the limit of solubility was exceeded, and that it would

be likely to adsorb on to solid materials. The high log P is indicative of strong adsorption (1).

No data were provided for hydrolysis on the grounds that the test could not be performed on the new substance due to low solubility in water and lack of sufficiently sensitive analytical methods. The substance contains an alkyl ester functionality but hydrolysis is expected to be slow under environmental conditions due to its very low water solubility.

No data were provided for dissociation constant on the grounds that results not measurable on compounds with low water solubility. The substance contains 3 nitrogens but these are unlikely to be basic.

4. PURITY OF THE CHEMICAL

Degree of purity: 98.7%

Impurities: 2 unknown impurities
Average value of each ranging from 0.4% to 0.8%

Additives/Adjuvants: None

5. INDUSTRIAL USE

C-1810 will be used in the manufacture of photographic film/paper. The estimated import volume is 2.5 to 3.1 tonnes per year.

6. OCCUPATIONAL EXPOSURE

C-1810 will be imported into Australia in powder form contained in pre-weighed units which will be stored until needed in shipping containers (size and type not provided) at the Kodak site in Coburg, Victoria.

C-1810 powder will be reformulated into a dispersion at the Kodak site. In the reformulation process, the powder in pre-weighed units will be added to the mixing tanks, and will be processed to form a dispersion. This dispersion will be chilled and stored in plastic bags until needed. The addition of the powder will take approximately 15 minutes each time and will be carried out approximately 25 times a year. Ten workers will be involved in this process.

The C-1810 dispersion is added to melt tanks along with other additives before being pumped to automated processing equipment where C-1810 is incorporated into photographic film and paper products. C-1810 will be trapped in the product.

Since 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. Significant risk of exposure to the notified chemical in the dispersion during storage is not anticipated. Potential exposure may occur during its manual handling. Operators may come into direct contact with the notified chemical during the emptying of the powder into the mixing tank, packing the suspension, adding the suspension to the melting tank, equipment cleaning, and during clean-up of accidental spillages. The major route of potential exposure for the powder is inhalational and for the dispersion is dermal.

7. PUBLIC EXPOSURE

Under correct usage, public exposure to the notified chemical will be negligible due to minimal release of the chemical into the environment. The chemical will be totally consumed in the manufacture of 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 (<0.1% w/w) in the film or paper, and according to the notifier, once the dispersion is incorporated in the film or paper it will be trapped in the product.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The notifier states that there are no anticipated releases to the environment of the pure chemical. Approximately 10 % (amount to be confirmed) of the dispersion containing C-1810 may be released to the municipal sewer. Further losses of about 10% are encountered when the dispersion is added to the emulsion and the

film is coated. However, this waste is routed through the silver recovery plant and from their physico-chemical properties the chemicals are likely to be absorbed to the removed solids from which silver (~10%) is recovered in Port Kembla and the remainder incinerated. The company is presently undertaking some analytical testing of the initial effluent, the recovered cake and the filtrate to confirm the amount released. The municipal sewer flow is routed for secondary treatment at the Werribee treatment facility. Less than 1% of wastes may be sent to a secured landfill.

8.2 Fate

C-1810 will mainly enter the environment when the dispersion containing the notified substance is discharged to the sewer. It would appear unlikely that C-1810 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-1810 in the soil, but prospects of leaching to any appreciable extent appear minimal, in view of the low water solubility and expected strong adsorption.

8.2.1 Biodegradation

Ready biodegradability was investigated using the modified Sturm test (OECD Guideline 301B) with measurement of evolved carbon dioxide. The extent of biodegradation amounted to a relatively low 10% in 28 days at nominal concentration of 10 ppm, and was even lower (3%) at 20 ppm. The results indicate that C-1810 is not readily biodegradable, with the negative figure suggestive of toxicity to sewage sludge microorganisms. However, the activated sludge respiration inhibition test (OECD Guideline 209) indicated that C-1810 does not inhibit respiration of microorganisms (3h IC50 > 100 $mg.L^{-1}$).

8.2.2 Bioaccumulation

As C-1810 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 (3). C-1810's molecular weight of 748 and its complex functionality indicates it has a low capacity to bioaccumulate (3). Further, as the log Pow value has been estimated as 6.2, these to bioaccumulate (3). Further, as the log Pow value has been estimated as 6.2, these considerations taken together would indicate that C-1810's bioaccumulation potential is likely to be low.

The possibility of soil accumulation needs consideration. However, C-1810 contains linkages such as the ester and amides 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 acute toxicity of C-1810

Test	Species	Dose	Outcome	Reference
Oral	Rat	5000 mg/kg	LD50>5000 mg/kg	4
Dermal	Rat	2000 mg/kg	LD50>2000 mg/kg	5
Skin Irritation	Rabbit	0.5 g	Non-irritating	6
Eye Irritation	Rabbit	0.1 g	Slightly irritating	7
Skin Sensitisation	Guinea Pig	100% induction 100% challenge	Non-sensitising	8

9.1.1 Oral Toxicity (4)

Charles River CD rats (5/sex) were given a single oral dose (by gavage) of C-1810 at 5000 mg/kg, suspended in an 0.5% aqueous solution of guar gum. The animals were observed for a period of 14 days following treatment. There were no deaths. Clinical signs were limited to a white discolouration of faeces in all animals on the day after dosing. No treatment-related gross changes were observed at necropsy. The acute oral LD50 in the rat was >5000 mg/kg.

9.1.2 Dermal Toxicity (5)

The acute dermal toxicity of C-1810 was investigated in Charles River CD rats. The rats (5/sex) were treated dermally with C-1810 moistened with distilled water at a dose of 2000 mg/kg. The chemical was applied to the clipped dorsal area under an occlusive bandage for 24 hours. The animals were observed for a period of 14 days following treatment. There were no deaths during the study. There were no treatment-related clinical signs and weight gain was normal. The acute dermal LD50 in the rat was >2000 mg/kg.

9.1.3 Skin Irritation (6)

C-1810 (0.5 g/animal), moistened with distilled water was applied for a period of 24 hours under occlusive dressing to a clipped area on each of three New Zealand white rabbits (sex not stated). The animals were observed at 1, 24, 48, 72 hours, and 7 and 14 days after removal of the dressing. There were no signs of irritation at any of the observation times. Therefore, the C-1810 appears to be non-irritating to skin.

9.1.4 Eye Irritation (7)

The ocular irritation potential of C-1810 was studied in New Zealand white rabbits (6 animals, sex not stated). The test substance (0.1 g of powder) was placed in the conjunctival sac of one eye per animal with the other eye acting as the control. Three animals had their eyes irrigated with distilled water immediately after application of the test substance, while the eyes of the other three animals were not washed. The eyes were examined at 1, 24, 48 and 72 hours after the instilling of the test substance. In the unwashed eyes, moderate erythema (3/3 animals) and slight (2/3) to moderate (1/3) oedema of the

conjunctivae and nictitating membranes, and slight erythema of the lids (3/3) were observed at one hour post-dosing. The irritation decreased over time and all unwashed eyes appeared normal by 72 hours. The effect of immediate washing of the eye was palliative. Therefore, C-1810 appears to be slightly irritating to the eye.

9.1.5 Skin Sensitisation (8)

C-1810 was tested for its potential to cause delayed contact hypersensitivity (Buehler method) in Hartley guinea pigs. A known sensitising agent, 1-chloro-2,4-dinitrobenzene was tested in this strain within 1 year of the current test for validation. An initial primary skin irritation study in 3 guinea pigs showed 0.5 g of the test substance not to cause any skin irritation. The minimum irritant concentration was not determined and the maximum non-irritant concentration was 100%. During the induction phase, the test material at 100% concentration was applied under occlusive bandage to the skin of guinea pigs (5/sex/group) for 6 hours. This procedure was repeated weekly for 3 weeks. One male died on day 22, seven days after the last induction dose. Necropsy of this animal did not show any evidence for a treatment-related effect. After a two week treatment-free period the challenge dose of 0.5 g (100% concentration) was applied to an area of the skin different to that used for induction. The animals were observed for a period of 48 hours after the challenge dose. There was no sign of erythema or oedema. Under the conditions of this experiment, C-1810 was shown to be non-sensitising.

9.2 Repeated Dose Toxicity (9)

C-1810 in corn oil was given by oral gavage to Charles River CD rats (5/sex/dose) at doses of 0, 100, 300 or 1000 mg/kg/day given 5 days per week for a total of 21 doses over a 28-day period. One female in the mid dose group was found dead on day 17, but this was considered not to be related to the treatment. There were no treatment-related clinical signs. The high dose males exhibited a slight decrease in body weight gain and at the end of the study the mean body weight in these males was 7% less than that of the control males. Food consumption was also slightly lower in the high dose males. Haematology, cell morphology and clinical chemistry did not reveal any treatment-related changes. At necropsy, there were no treatment-related changes in organ

weights, and gross pathology and histology did not reveal any changes.

9.3 Genotoxicity

9.3.1 Reverse Mutation Assay in Salmonella *typhimurium (10)*

C-1810 was tested for its potential to cause gene mutations in Salmonella typhimurim tester strains TA1535, TA1537, TA1538, TA98 and TA100. A preliminary dose range-finding assay using the TA100 strain showed the test substance not to decrease the number of revertant colonies per plate or the appearance of the background lawn at concentrations of up to 10,000 µg/plate both in the presence or absence of rat liver S9 mix. Consequently, a dose range of 333 to 10,000 µg/plate was used for the main test. No increase in the frequency of revertant colonies was seen in any of the tester strains when C-1810 was tested both in the presence or absence of S9 mix. Suitable positive controls were used. Therefore, C-1810 does not appear to mutagenic in bacteria under these experimental conditions.

9.3.1 Mouse Micronucleus Assay (11)

C-1810 was evaluated for its ability to induce *the f*ormation of micronuclei in bone marrow polychromatic erythrocytes of ICR mice in vivo. The test substance suspended in corn oil was given to mice (5/sex/dose/time point) by gavage at a single dose of 0, 500, 2500 or 5000 mg/kg. These dose levels were chosen on the basis of a preliminary study where doses of up to 5010 mg/kg were shown not to cause any deaths or signs of toxicity for up to 72 hours post-dosing. Cyclophosphamide was used a s a positive control. In the main study, the animals were killed at 24, 48 or 72 hours post-dosing and the bone marrow was examined. Examination of the bone marrow, revealed no treatment-related increase in the number of micronucleated polychromatic erythrocytes with the test substance at any of the examination time points. Under the conditions of this test, C-1810 was not associated with the induction of micronuclei in mouse bone marrow.

9.4 Overall Assessment of Toxicological Data

The notified substance, C-1810, was tested for acute oral (LD50 >5000 mg/kg) and dermal (LD50 >2000 mg/kg) toxicity in rats and was shown to have low acute toxicity. C-1810 was found to

have low skin irritation potential rabbits. In the rabbit eye the chemical was found to cause reversible, moderate erythema (3/3 animals) and slight (2/3) to moderate (1/3) oedema of the conjunctivae and nictitating membranes, and slight erythema of the lids (3/3) at one hour post-dosing. A skin sensitisation test using the Buehler method showed C-1810 not to cause an allergic reaction when a dermal induction and challenge dose of 0.5 g (100% concentration) was used, indicating that C-1812 was not a skin sensitiser..

A 28-day repeated dose toxicity study with the notified substance in rats showed the only signs of toxicity to be a slight retardation of body weight gain and a decrease in food consumption in the males treated at up to 1000 mg/kg/day.

C-1810 was tested in two genotoxicity studies. In the reverse mutation assay in Salmonella typhimurium (Ames test) C-1810 did not increase the frequency of revertant colonies, indicating that it was not mutagenic. In the mouse micronucleus assay, C-1810 was shown not to induce the formation of micronuclei in polychromatic erythrocytes, indicating a low potential for causing chromosomal damage.

Overall, the toxicity data for C-1810 show it to be of low acute toxic potential and unlikely to pose a significant acute health risk to humans.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Test	**Result**
Acute toxicity in Fathead minnow	*96 h LC50* > 59 mg.L-1 NOEC = 59 mg.L-1
Acute toxicity in Daphnia magna	48 h EC50 > 59 mg.L-1 NOEC = 59 mg.L-1

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

Concentrations tested (0.59, 5.9 & 59 mg.L-1) for fathead minnows and Daphnia all exceeded the aqueous solubility of C-1810 and undissolved material was observed throughout in *all so*lutions. Although the actual concentrations are unclear, fathead minnows

and Daphnia are unlikely to suffer acute effects up to the limit of solubility (calculated as 35 ppb) of C-1810.

The above results indicate that C-1810 is practically non-toxic to aquatic fauna. While reproduction tests for daphnids were not conducted, the apparent lack of acute toxicity and the probability the 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.

Algal tests were similarly not conducted, but significant exposure of algae is 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.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Up to 0.5 tonne (to be confirmed) of C-1810 may be discharged to sewage treatment works per annum where it is likely to adsorb to sludge or soil. It should be noted that several new chemicals (with similar physico-chemical properties) will be used during the one product run, resulting in Kodak releasing approximately 3.6 tonne of chemicals per annum to the sewer. This is a worst case assuming 20% is discharged to the sewer.
Discussions with the notifier as well as Melbourne Water and a site visit has indicated that an active program aimed at identifying and reducing the amount of discharge of this chemical and others of a similar type. The notifier is currently renegotiating with Melbourne Water the amount of treated effluent allowed to be discharged.

As noted above, the dispersion is made up above 25 times per year and assuming equal lots about 20 kg per batch is discharged, the following "worst case" calculation, using company estimates, indicates the final concentration reached will be 1.4 ppb.

concentration in dispersion = 90 g.kg-1
rate of dilution in Kodak sewer = 10-4
concentration in sewer as it leaves Kodak = 9 ppm
flow rate of Kodak sewer at exit point = 4 x 105 L/day
flow rate (average) into Werribee = 5 x 108 L/day
concentration reaching Werribee = 7.2 ppb
rate of dilution in receiving waters = 5 - 25 times
final concentration = 1.4 - 0.3 ppb

This calculation assumes there will be no losses due to adsorption to sediment etc. The concentration is an order of magnitude lower than the calculated water solubility. While aquatic organisms were exposed to levels several orders of magnitude higher than this with no apparent effects, this was largely due to undissolved materiain with the Werribee sewerage complex, adsorbed to either sediments or soil, and the expected exposure to natural organisms and bioaccumulation is likely to be low. Therefore, C-1810 is likely to present a low hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

To date, no information on the effects of C-1810 on human health have been reported. Animal tests indicate that C-1810 has low acute toxicity.

C-1810 is combustible and is therefore 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, the exposure to C-1810 is expected to be minimal. It is unlikely that the notified chemical will present any significant acute health or safety hazard to workers.

13. RECOMMENDATIONS

To minimise exposure to C-1810, the following guidelines and precautions should be observed:

. storage of the powder and dispersion forms of C-1810 should be in robust, tightly sealed containers.

. good work practices should be implemented to avoid the generation of a dust cloud, splashings or spillages;

- engineering control procedures such as dust extraction devices should be employed in areas where C-1810 powder is handled in the open;

- disposable dust masks, safety glasses complying with AS 1336 (12) and AS 1337 (13), close fitting overalls, and PVC gloves complying AS 2161 (14) should be used during weigh-up and fill-off activities. In situations where the ventilation is insufficient, an approved respirator should be used;

- 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;

- spillages should be cleaned up promptly during clean-up of powder spillage, an approved respirator, safety glasses, close fitting overalls and PVC gloves should be used. Fine powder should be collected with a suitable vacuum cleaner, insuring the minimum amount of dust is generated. During clean-up of the dispersion form, safety glasses, close fitting overalls and PVC gloves and a PVC apron should be use;

- good personal hygiene should be observed.

- a copy of the Material Safety Data Sheet for the notified chemical should be easily accessible to employees.

- the company, in conjunction with Melbourne Water, should look at ways of minimising the discharge of this chemical into the sewage system.

14. MATERIAL SAFETY DATA SHEET (MSDS)

The Material Safety Data Sheet for C-1810 (Attachment 1) was provided in Worksafe Australia format (15). 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-1810 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. et al., *Handbook of Chemical Property Estimation Methods*, McGraw-Hill, 1982, pp 2-15, pp 4-9.

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3. Connell D. W., *Bioaccumulation of Xenobiotic Compounds*, CRC Press, 1990, p 56.

4. Acute Oral Toxicity of C-1810, Eastman Kodak Company, Rochester, NY, Report No. 261949Y, 1989.

5. Acute Dermal Toxicity of C-1810, Eastman Kodak Company, Rochester, NY, Report No. 261950S, 1989.

6. Acute Dermal Irritation of C-1810, Eastman Kodak Company, Rochester, NY, Report No. 261951T, 1989.

7. Acute Eye Irritation of C-1810, Eastman Kodak Company, Rochester, NY, Report No. 261988K, 1989.

8. Skin Sensitization Study (Buehler Method) of C-1810, Eastman Kodak Company, Rochester, NY, Report No. 261952U, 1989.

9. Four Week Oral Toxicity of C-1810 in the Rat, Eastman Kodak Company, Rochester, NY, Report No. 248848V, 1990.

10. Mutagenicity test on C-1810 in the Ames Salmonella/Microsome Reverse Mutration Assay, Hazelton Laboratories, Maryland, USA, Study No. 10803-0-401, 1989

11. Mutagenicity test on C-1810 *In Vivo* Mouse Micronucleus Assay, Hazelton Laboratories, Maryland, USA, Study No. 10803-0-455, 1989

12. Australian Standard 1336-1982, "Recommended Practices for Eye Protection in the Industrial Environment", Standards Association of Australia Publ., Sydney, 1982.

13. Australian Standard 1337-1984, "Eye Protectors for Industrial Applications", Standards Association of Australia Publ., Sydney, 1984.

14. Australian Standard 2161-1978, "Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)", Standards Association of Australia Publ., Sydney, 1978.

15. National Occupational Health and Safety Commission, Guidance Note for the Completion of a Material Safety Data Sheet, 2nd, edition, AGPS, Canberra, 1990.