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NATIONAL INDUSTRIAL CHEMICALS
NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

C-1811

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

C-1811

1. APPLICANT

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

2. IDENTITY OF THE CHEMICAL

Trade name(s): C-1811

Molecular weight: 579.8

Based on the data provided, C-1811, is considered to be non-hazardous. Therefore, the following details have been exempted from publication:

. chemical name
. CAS Number
. molecular formula
. structural formula
. spectral data

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: white powder

Melting Point/Boiling Point: 141.4°C ± 0.2°C

Specific Density: 1,175kg/m^3

Water Solubility: 1.7 x 10^{-2}mg L^{-1} (51 ppb)

Partition co-efficient: (n-octanol/water) log Kow = 6.0

Combustibility:	combustible, but not highly flammable, or pyrophoric
Hazardous Combustion Products:	oxides of carbon, nitrogen and sulfur
Explosive Properties:	not explosive
Reactivity/Stability:	incompatible with strong oxidizers and decomposition products include methane and oxides of carbon.
Particle size distribution:	range - 38 - 2360 µm mean - 288 µm

Comments on physicochemical properties:

Partition coefficient was calaulated according to the procedures outlined in OECD Test Guideline 117. From this value, the water solubility was calculated using the equation:

$\log(1/S) = 1.339 \log Kow - 0.978 + 0.0095 (t_m - 25)$;
where t_m is the melting point in ^oC and S is in moles/L (1a).

No data were provided for hydrolysis on the grounds that the test could not be performed on the new substance due to low water solubility, and lack of sufficiently sensitive analytical methods. The notified chemical appears to lack readily hydrolysable functionalities.

No data were provided for adsorption/desorption on the grounds that results are not measurable on compounds with low water solubility. It should be noted that similar notified compounds were seen to adhere to surfaces in vessels in which the limit of water solubility was exceeded. The high log P is indicative of strong adsorption (1b).

No data were provided for dissociation constant on the grounds that results are not measurable on compounds with low water solubility. The substance has a carboxylic acid functionality and one nonbasic nitrogen. Based on that for acetic acid glacial, the Ka is expected to be in the order of 10^{-5} (2).

The vapour pressure for a chemical substance of this molecular weight is not relevant.

Data on Flash point, Flammability limits and Autoignition temperature are not required for a chemical of this type.

4. METHOD OF DETECTION AND DETERMINATION:

High performance liquid chromatography (HPLC) may be used for detecting the notified chemical.

5. PURITY OF THE CHEMICAL

Degree of purity: 99.2%]% area by HPLC
Impurities (unidentified): 0.8%]
(4 impurities totaleing 0.8%)

Additives/Adjuvants: none

6. INDUSTRIAL USES

The notified chemical will be imported in quantities of less than 750 kg per annum.

Manufacture or reformulation of the chemical will not occur in Australia. The use of the notified chemical will occur at only one site, in Melbourne. The notified chemical will be used in the manufacture of photographic film/paper.

7. OCCUPATIONAL EXPOSURE

7.1. Number/category of workers to be involved:

Number	Category	Chemical Form
10	Operator	Dry & Dispersion
25	Operator	Dispersion

7.2. Nature of work

The notified chemical will be imported into Australia in pre-weighed units, and not require re-weighing within Australia. The pre-weighed chemical will be added to mix tanks approximately 25 times per year; the addition of the dry notified chemical may take 15 minutes each time. Other addenda will be added to the mix tank, which will result in a dispersion. The dispersion will be chilled and stored in closed plastic bags for upto several weeks. The dispersions will be taken from the store and added to melt tanks, where other addenda will be added. The dispersion with other addenda will then be pumped to closely-controlled

automated equipment where the notified chemical will be incorporated into articles.

The notifier informs that once the notified chemical becomes part of the article, there will be no chance of potential exposure to the notified chemical.

8. PUBLIC EXPOSURE

The potential for public exposure to C-1811 is low. The notifier has indicated that some 20% of the aqueous dispersion containing C-1811 could be released into the municipal sewer. The notifier has also indicated that the concentration of C-1811 in the municipal sewer is approximately 1 in 10000. Additionally, less than 1% of waste may be sent to secured landfill.

C-1811 is not classified as a Dangerous Good by the Australian Code for the Transport of Dangerous Goods. The pure chemical is stored in sealed shipping containers, where it is to be transported on trolleys to the using area. The dispersion will be stored in closed plastic bags in chilled storage areas.

9. ENVIRONMENTAL EXPOSURE

9.1 Release

The company states there are no anticipated releases to the environment of the pure chemical. Approximately 10% (could be < 6% - to be confirmed) of the dispersion containing C-1811 could be released to the municipal sewer. Further losses of about 10% are encountered when the film is coated. However, this waste is routed through the silver recovery plant and from its physico-chemical properties the notified chemical is 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 this. 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.

9.2 Fate

C-1811 will mainly enter the environment when the dispersion containing the notified substance is discharged to the sewer. No biodegradation studies were provided by the notifier. 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-1811 in the soil, but prospects of leaching to any appreciable extent appear minimal. in view of the low water solubility and expected strong adsorption.

. Bioaccumulation

As C-1811 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-1811's molecular weight of 579 indicates it has some capacity to bioaccumulate, but the molecular weight is at the upper end of this range of concern, and the presence of carbamate, ether and other linkages should further moderate the bioaccumulation potential (4). Further, as the log Pow value has been estimated as 6.0, these considerations taken together would indicate that C-1811's bioaccumulation potential is likely to be low.

10. EVALUATION OF TOXICOLOGICAL DATA

10.1 Acute Toxicity

The acute toxicity studies have been conducted with the notified chemical in the powder form.

Table 1 Summary of acute toxicity of C-1811

Test	**Species**	**Dose**	**Outcome**	**References**
Oral	Rat	5000mg/kg	LD_{50}: >5000 mg/kg	5
Dermal	Rat	2000mg/kg	LD_{50}: >2000 mg/kg	6
Skin Irritation	Rabbit	0.5 g	non-irritant	7
Eye Irritation	Rabbit	0.1 g	slight irritant	8
Skin Sensitisation	Guinea pig	0.5 g	non-sensitising	9

10.1.1 Oral Toxicity (5)

This limit test was performed according to the OECD Guidelines for Testing Chemicals, Section 4: Health Effects, No. 401.

The notified chemical was added to the vehicle, 0.5% aqueous suspension of guar gum and was administered as a 20% suspension in the vehicle. A single 5000 mg/kg dose of C-1811 was administered by gavage to five male and five female rats. The animals were observed for 14 days. No deaths occurred during the study. Clinical signs observed in the animals included white faeces from all the animals on the day after dosing. By Day 2 of the study, all animals appeared clinically normal. During the first week of the study, the body weight of one of five males was reduced. Dehydration was also noted in this animal on Day 7 of the study. By Day 8, this male appeared clinically normal, and by end of the 14-day observation period, a normal weight gain was recorded. Necropsy revealed no gross pathological changes.

Results of this study indicate an acute LD_{50} of >5000 mg/kg in rats of both sexes for C-1811 (5).

10.1.2 Dermal Toxicity (6)

This limit test was performed according to the OECD Guidelines for Testing Chemicals, Section 4: Health Effects, No. 402.

The notified chemical was moistened with distilled water. A single 2000mg/kg dose of C-1811 was placed on a fiber pad which was then applied to the shaved backs of five male and five female rats and covered with a semi-occlusive dressing. Twenty-four hours after the application the dressing was removed. The treated skin was washed with water, dried and skin reaction was assessed. The animals were observed for 14 days. No deaths occurred during the study. No abnormal clinical signs were observed at any time during the study. No necropsies were performed.

Results of this study indicate an acute dermal LD_{50} of >2000 mg/kg in rats of both sexes for C-1811 (6).

10.1.3 Skin Irritation (7)

This study was carried out in accordance with the OECD Guidelines for Testing Chemicals, Section 4: Health Effects, No. 404.

A single dose of 0.5 g of C-1811 (moistened with distilled water) was applied to the intact skin of the shaved backs of three rabbits (male or female). The application site was covered with a fiber pad. The pad was covered with a semi-occlusive dressing for four hours. After the treatment period the dressing was removed and the skin was washed with water. The skin reaction was assessed at 1, 24, 48, 72 hours, and 7 and 14 days after removal of the occlusive patch. No signs of erythema or oedema were observed. No irritant response was seen at any time during the study. No corrosive effect was evident on the skin.

The results of this study indicate that C-1811 is not a skin irritant in rabbits at the concentration tested (7).

10.1.4 Eye Irritation (8)

This study was carried out in accordance with the OECD Guidelines for Testing Chemicals, Section 4: Health Effects, No. 405.

The test material C-1811, 0.1 g, was placed in the conjunctival sac of the one eye of each of six rabbits (of either sex). The other eye remained untreated and served as the reference control. Three of the treated eyes were immediately washed with running distilled water; the other three eyes were not washed. The eyes of each animal were examined 1, 24, 48 and 72 hours after administration. Eyes were treated with a 2% ophthalmic solution of fluorescein at 24 hours and observed for staining. In unwashed eyes, signs of irritation were limited to slight erythema of the conjunctivae and nictitating membranes at the one-hour and 24-hour observation periods. No staining was evident when these eyes were tested with fluorescein dye 24 hours after administration of the notified chemical. At the 48-hour observation period, all unwashed eyes appeared clinically normal. No necropsies were performed.

The results of this study indicate that C-1811 is a slight eye irritant in rabbits at the concentration tested (8).

10.1.5 Skin Sensitisation (9)

This study was carried out in accordance with the OECD Guidelines for Testing Chemicals, Section 4: Health Effects, No. 406, using the Buehler Study Design Test (10).

From a preliminary study, the minimal irritant concentration was not determined and the maximal non-irritant concentration was determined as 100% of the notified chemical. Three guinea pigs were tested at this concentration. The material was administered only as a solid moistened with water. In the induction and challenge study, 20 guinea pigs (10 males and 10 females) were used of which 10 (5 males and 5 females) served as controls.

Induction and Challenge Procedure

The test material (0.5 gm) was applied to a fiber pad. The backs of the guinea pigs were clipped before application of the test material. Pads were held in place by placing a wrap around the torso of the animal and securing it in place. The patches were left in place for six hours, after which they were removed and

the skin wiped free of excess material. This procedure was repeated weekly for three weeks. Two weeks after the last induction exposure, the maximal non-irritant concentration, 100% of the notified chemical was applied to the backs of the 10 guinea pigs using the same procedure, except that the patches were applied to the backs on the opposite side of the midline from the side used for induction. To differentiate dermal irritation from sensitisation, the remaining 10 previously untreated animals were subjected to the same challenge procedure. Observations were made 24 and 48 hours after application and scored for signs of dermal reaction (11).

No signs of erythema or oedema were observed in any of the irritation control or induction and challenge groups. The absence of a response indicated that the animals had not been sensitised to the notified chemical. A sensitisation study by the Buehler method (11) with the known sensitising agent, 1-chloro-2,4-dinitrobenzene, was conducted with this strain of guinea pig for method validation. This material produced a positive sensitisation response.

The results of this study indicate that C-1811 is not a skin sensitiser in guinea pigs (9).

10.2 Mutagenicity

Summary of mutagenicity of C-1811

Test	**Species**	**Dose Range**	**Outcome**	**Reference**
Reverse Mutation	*Salmonella typhimurium*	10-10000 µg/plate	negative	12
In vivo Micronucleus Assay	Mice	500-5000 mg/kg	negative	13

10.2.1 *Salmonella typhimurium*, Reverse Mutation Assay (12)

This Ames test was carried out according to the OECD Guidelines for Testing Chemicals, Section 4, No. 471.

C-1811 at concentrations of 10, 100, 333.3, 1000, 5000 and 10,000 µg/plate was tested in two independent experiments for gene mutation according to the direct plate incorporation method. *Salmonella typhimurium* strains TA 1535 and TA 100 were used to indicate base pair mutations, and TA 1537, TA 1538 and TA 98 to indicate frame-shift mutations. Untreated and solvent (dimethylsulfoxide) test plates were used as negative controls. The test article plates and the negative control plates were performed both in the presence and absence of microsomal activation (S9 liver microsome mix). Positive controls included sodium azide and 2-nitrofluorene, both without metabolic activation, and 2-aminoanthracene with metabolic activation. All tests were performed in triplicate.

No dose-related increase in the number of revertant colonies was observed in any of the strains exposed to C-1811 or in the negative controls, in the presence and absence of metabolic activation. In contrast, the positive controls showed marked increases in the number of revertant colonies. The plates incubated with the test article showed normal background growth up to 5000.0 µg/plate with and without S9 mix in all strains used.

The results of this experiment indicate that the notified chemical did not produce mutations in *Salmonella typhimurium* under the conditions of the study (12).

10.2.2 *In vivo* Mouse Micronucleus Assay (13)

This study was carried out according to the OECD Guidelines for Testing Chemicals, Section 4, No. 474.

The notified chemical was suspended in corn oil and administered to ICR mice by oral gavage at 500, 2500 and 5000 mg/kg based on the results of a previously conducted dose range finding assay where the maximum tolerated dose was estimated to be >5000 mg/kg. The animals were euthanatized 24, 48 and 72 hours after dosing for extraction of the bone marrow. Ten animals (five males and five females) were randomly assigned to each dose/harvest time group. A positive control group was euthanatized 24 hours after

dosing (receiving cyclophosphamide). All animals appeared normal after dosing and the notified chemical induced no significant increases in micronucleated polychromatic erythrocytes (PCE) over the levels observed in the vehicle controls in either sex at any of the harvest times. The positive control induced significant increases in micronucleated PCEs in both sexes.

C-1811 did not induce a significant increase in micronuclei in bone marrow PCE under the conditions of this assay and is considered non-clastogenic in the Mouse Micronucleus Test (13).

10.3 Overall Assessment of Toxicological Data

C-1811 has low oral toxicity (Oral LD_{50} in rats: >5000 mg/kg) and low acute dermal toxicity (dermal LD_{50} in rats: >2000 mg/kg). Tests in rabbits reveal that it is not a skin irritant, but is a slight eye irritant. It has been found to be a non-sensitiser in guinea pigs.

C-1811 was found to be non-genotoxic in both the *Salmonella typhimurium* reverse mutation test and the *in-vivo* Mouse Micronucleus Assay.

11. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notified chemical being a low volume chemical substance, it is not a requirement that environmental effect studies are submitted. However, an activated sludge respiration inhibition test (OECD TG 209) indicated that C-1811 was not toxic (NOEC 50 $mg.L^{-1}$, highest dose tested) to the micro-organisms tested.

12. ASSESSMENT OF ENVIRONMENTAL HAZARDS

Up to 150 kg (to be confirmed) of C-1811 may be discharged to sewage treatment works per annum where it is likely to adsorb to sludge or soil. It should be noted that a number of 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 worse case assuming 20% is discharged to the sewer. Discussions with the company as well as Melbourne Water, including a site visit, has indicated that the company has initiated an active program aimed at identifying and reducing the amount of these discharged chemicals. This includes a renegotiation with Melbourne Water of the amount of treated effluent allowed to be discharged.

As noted above, the dispersion is made 25 times per year and assuming equal lots about 6 kg per batch will be discharged. Assuming a "worst case", using the following calculation, the company estimates indicates that final concentration reached will be 0.5 ppb.

rate of dilution in Kodak sewer	=	10^{-4}
concentration in sewer as it leaves Kodak	=	3 ppm
flow rate of Kodak sewer at exit point	=	4×10^5 L/day
flow rate (average) into Werribee	=	5×10^8 L/day
concentration reaching Werribee	=	2.4 ppb
rate of dilution in receiving waters	=	5 - 25 times
final concentration	=	0.5 - 0.1 ppb

The calculation assumes there will be no losses due to adsorption to sediment etc. Although the concentration of C-1811 is in the order of ppb, C-1811 is unlikely to bioaccumulate to levels that could be toxic to aquatic organisms. However, accumulation in soils and sediments at the Werribee treatment facility is possible.

13. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY

C-1811 has low oral toxicity (Oral LD_{50} in rats: >5000 mg/kg) and low acute dermal toxicity (dermal LD_{50} in rats: >2000 mg/kg). C-1811 is not a skin irritant or a skin sensitiser. The notified chemical is a slight eye irritant in the eyes of rabbits. Skin and eye contact should be avoided and the recommendations under Section 13 should be followed to minimise exposure.

Due to low public and occupational exposure under normal use conditions, it is unlikely that the notified chemical will pose any health or safety hazard to the public and workers.

14. RECOMMENDATIONS FOR THE CONTROL OF PUBLIC, WORKER AND ENVIRONMENTAL EXPOSURE

To minimise public, worker and environmental exposure to C-1811 the following guidelines and precautions should be observed:

. suitable personal protective equipment which comply with Australian Standards (AS) should be worn such as:

  - safety glasses (AS 1337) - *Eye protectors for Industrial Applications* (14);

  - impervious elbow length gloves (AS 2161) - *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)* (15);

  - appropriate impervious protective clothing (AS 3765) - *Clothing for protection against Hazardous Chemicals* (16);

. good work practices should be implemented to avoid splashings or spillages during formulating and using products;

. good housekeeping and maintenance should be practised. Spillages should be cleaned up promptly using absorbents;

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

. The company in conjunction with Melbourne Water, should continue to look at ways of minimising the amount of these chemicals discharged to the sewer.

15. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for C-1811 (Attachment 1) was provided in Worksafe Australia format (17). This MSDS was provided by Kodak (Australasia) Pty. Ltd as part of their notification statement. It is reproduced here as a matter of record. The accuracy of this information remains the responsibility of Kodak (Australasia) Pty. Ltd.

16. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of C-1811 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

17. REFERENCES

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5. Acute oral Toxicity of C-1811. Toxicological Sciences Laboratory-Eastman Kodak Lab., Rochester Report - 261999P, 1990.

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12. *Salmonella Typhimurium* Point Mutation Assay with C-1811, Hazeton Laboratories America, Inc. Kensington, Maryland Project ID 10951-0-401.

13. Mouse Micronucleus Assay *In Vivo* with C-1811, Hazeton Laboratories America, Inc. Kensington, Maryland Project ID 10951-0-455.

14. Australian Standard 1337 - 1984 *Eye protectors for Industrial Applications,* Standards Association of Australia Publ., Sydney (1984).

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16. Australian Standard 3765-1990 *Clothing for Protection Against Hazardous Chemicals*, Standards Association of Australia Publ., Sydney (1990).

17. National Occupational Health and Safety Commission, *Guidance Note for the Completion of a Material Safety Data Sheet,* 2nd. Edition, AGPS, Canberra, 1991.