File No: NA/50

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

C-1812

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

4-[N-[1-(7-Chloro-6-methyl-1H-pyrazolo(5,1-c)-1,2,4-triazol-3-yl)tridecyl]-N-octylamino]-4-oxobutanoic acid

1. APPLICANT

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

2. IDENTITY OF THE CHEMICAL

Based on the data provided, C-1812 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: 566.2 g/mol

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: Off-white powder

Melting Point/Boiling Point: 83.0-85.0 °C

Particle Size: 177 µm (mean), 38 µm (minimum)

Specific Gravity/Density: 1,111 kg/m^3

Vapour Pressure: 4.12 x 10-5 Pa at 25°C (Balance method)

Water Solubility: 1.2 ppb (calculated)

Fat Solubility: 313.5 mg/100 g of fat at 30°C

Partition Co-efficient: (n-octanol/water)	log Kow = 7.2 at 23°C
Hydrolysis as a function of pH:	Half-life at 25°C ~ 11 days at pH 4 ~ 131 days at pH 7 ~ 10 days at pH 9
Adsorption/Desorption:	Not determined
Dissociation Constant:	Not determined
Flash Point:	Not applicable to solids
Flammability Limits:	Negative at 27°C
Pyrolysis products:	methane, ammonia, oxides of carbon, oxides of nitrogen and HCl gas.
Autoignition Temperature:	>400°C
Explosive Properties:	Non-explosive
Reactivity/Stability:	Not an oxidising agent. Incompatible with strong oxidising agents.

Comments on Physical and Chemical Properties:

The partition coefficient was estimated according to a High Pressure Liquid Chromatography (HPLC) procedure outlined in OECD Test Guideline 117. From this value, Kodak calculated the water solubility using the equation:

$\log(1/S) = 1.339 \log Kow - 0.978$; where S is in moles/L (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 partition coefficient is indicative of strong adsorption (1).

Low water solubility similarly precluded measurement of the dissociation constant. The substance contains a carboxylic acid functionality and also 4 heteroatoms but it is unclear whether the heteroatoms are basic and the substance is amphoteric in nature.

4. PURITY OF THE CHEMICAL

Degree of purity: 98%

Impurities: 5 unknown impurities
Average value of each ranging from 0.2% to 0.8%

Additives/Adjuvants: None

5. INDUSTRIAL USES

C-1812 will be used in the manufacture of photographic film/paper. The estimated import volume is 2.4 to 2.9 tonnes per annum.

6. OCCUPATIONAL EXPOSURE

C-1812 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-1812 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-1812 dispersion is added to melt tanks along with other additives before being pumped to automated processing equipment where C-1812 is incorporated into photographic film and paper products. C-1812 will be will 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 remain 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-1812 may be released to the municipal sewer. Further losses of about 10% would be 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 notifier 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.

8.2 Fate

C-1812 will mainly enter the environment when the dispersion containing the notified substance is discharged to the sewer. It would appear unlikely that C-1812 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-1812 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 (-9%) at 20 ppm. The results indicate that C-1812 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-1812 does not inhibit respiration of microorganisms (3h IC50 > 100 $mg.L^{-1}$).

8.2.2 Hydrolysis

The notifier has provided a study (OECD Guideline 111) on the hydrolysis of C-1812. The half-lives of C-1812 are as follows:

Approximate half-life (hours)

pH	25°C	50°C	55°C	65°C
4	259	78	35	33
7	3150	214	130	51
9	243	60	35	26

The above results indicate C-1812 is not persistent in water except at pH 7 and 25°C where it is moderately persistent. The pH of water in sewers is likely to range from pH 6-10 and it is unclear whether C-1812 will hydrolyse to a significant extent before it reaches the Werribee sewerage treatment complex.

8.2.3 Bioaccumulation

As C-1812 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-1812's molecular weight of 566 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 (3). Further, as the partition coefficient has been estimated as 7.2, these considerations taken together would indicate that C-1812's bioaccumulation potential is likely to be low.

The possibility of soil accumulation needs consideration. However, C-1812 has been shown to undergo gradual hydrolysis in sterile media, and 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 acute toxicity of C-1812

Test	Species	Max. Dose	Outcome	Reference
Oral	Rat	5000 mg/kg	LD50>5000 mg/kg	5
Dermal	Rat	2000 mg/kg	LD50>2000 mg/kg	6
Skin Irritation	Rabbit	0.5 g	Non-irritating	7
Eye Irritation	Rabbit	0.1 g	Slightly irritating	8
Skin Sensitisation	Guinea Pig	100% induction 100% challenge	Non-sensitising	9

9.1.1 Oral Toxicity (4)

Charles River CD rats (5/sex) were given a single oral dose (by gavage) of C-1812 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 included diarrhoea in 3/5 males, and light brown discolouration of faeces in all animals on the day of dosing. One female showed a weight loss of 21 g in the second week and had an enlarged right kidney with hydronephrosis, calculi in the pelvis of the left kidney, and dilation of the right ureter. No histological examination was conducted. It is not clear if these changes were treatment-related. The acute oral LD50 of C-1812 in rats was >5000 mg/kg.

9.1.2 **Dermal Toxicity** (5)

The acute dermal toxicity of C-1812 was investigated in Charles River CD rats. The rats (5/sex) were treated dermally with C-1812 moistened with distilled water and applied at a dose of 2000 mg/kg. The chemical was applied under an occlusive bandage for 24 hours to a clipped dorsal area of each rat. 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 of C-1812 in rats was >2000 mg/kg.

9.1.3 **Skin Irritation** (6)

C-1812 (0.5 g), moistened with distilled water was applied for a period of 24 hours under occlusive dressing to a clipped area of each of three New Zealand white rabbits. 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 test substance appears to be non-irritating to the skin.

9.1.4 **Eye Irritation** (7)

The ocular irritation potential of C-1812 was studied in New Zealand white rabbits. The test substance (0.1 g of powder) was placed in the conjunctival sac of one eye of each 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 application of the test substance. In the unwashed eyes, slight (1/3) to moderate (2/3) erythma of the adnexa was observed after the first hour. The irritation decreased over time and all unwashed eyes appeared normal by 72 hours. The

effect of immediate washing of the eye was palliative. C-1812 was slightly irritating to the eye.

9.1.5 **Skin Sensitisation** (8)

C-1812 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 tested positive in this strain within 1 year of the current test for validation. An initial primary skin irritation study in 3 guinea pigs showed a 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. 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. C-1812 does not appear to cause delayed skin sensitisation under these experimental conditions.

9.2 **Repeated Dose Toxicity** (9)

C-1812 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. 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 lower than that of the control males on several occasions during the study, with the greatest difference being observed on day 4 (the first investigation time point). Haematology did not reveal any treatment-related changes. Clinical chemistry showed a 2-fold and 1.5 fold increase in the mean serum alanine aminotransferase (ALT) levels in the high dose males and females, respectively. The increase in ALT may be indicative of liver toxicity. 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-1812 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 up to a concentration of 10,000 µg/plate both in the presence or absence of rat liver S9 mix. Consequently, a dose range of 100 to 10,000 µg/plate was used for the main test. There was no increase in the frequency of revertant colonies with any of the tester strains when C-1812 was tested both in the presence or absence of S9 mix. Suitable positive controls were used. Therefore, C-1812 does not appear to be mutagenic in bacteria under these experimental conditions.

9.3.1 Mouse Micronucleus Assay (11)

C-1812 was evaluated for its ability to induce the formation 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 oral gavage at a single dose of 0, 500, 2500 or 5000 mg/kg. These doses levels were chosen on the basis of a preliminary study where doses of up to 5000 mg/kg were shown not to cause any deaths or signs of toxicity for up to 72 hours after administration of the chemical. In the main study, the animals were killed at 24, 48 or 72 hours post-dosing and the bone marrow was examined. One mid-dose female was found dead at 48 hours. Another female was observed to have a distended axilla and died at approximately 55 hours after dosing. The mid- and high-dose males exhibited rough coats 4 hours after dosing and this condition remained until 48 hours post-dosing. On examination of the bone marrow, there were no significant increases in the frequency of micronucleated polychromatic erythrocytes with the test substance at any of the examination time points. Cyclophosphamide was used as a positive control. The results indicate that the administration of C-1812 to mice does not appear to induce the formation of micronuclei under these experimental conditions.

9.4 Overall Assessment of Toxicological Data

The notified substance, C-1812 was tested for acute oral (LD50 >5000 mg/kg) and dermal (LD50>2000 mg/kg) toxicity in rats and was shown to possess low acute toxicity. C-1812 was found to have a low skin and eye irritation potential in rabbits, with slight to moderate, reversible erythema of the adnexa being observed. The erythema may have been due to the abrasive nature of the powder. A skin sensitisation test in guinea pigs using the Buehler method showed C-1812 not to cause an allergic reaction when a dermal induction and challenge dose of 0.5 g (100% concentration) was used.

A 28-day repeat-dose toxicity study with the notified substance in rats showed only a slight retardation of body weight gain and a decrease in food consumption in the males treated at up to 1000 mg/kg/day. There was also a slight increase in the serum alanine transferase levels (ALT) in the high dose males and females. The increase in ALT levels may be indicative of liver toxicity, but this was not supported by histopathological examination.

C-1812 was tested in two genotoxicity studies. In the reverse mutation assay in *Salmonella typhimurium* (Ames test) C-1812 did not increase the frequency of revertant colonies, indicating a low potential for causing gene mutation. In the mouse micronucleus assay, C-1812 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-1812 show it to have low toxic potential and unlikely to pose a significant acute health risk to human.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Test	Result
Acute toxicity in Fathead minnow	96h LC50 > 54 $mg.L^{-1}$ NOEC > 54 $mg.L^{-1}$
Acute toxicity in *Daphnia magna*	48h EC50 > 54 $mg.L^{-1}$ NOEC < 0.54 $mg.L^{-1}$

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

Concentrations tested (0.54, 5.4 & 54 $mg.L^{-1}$) for fathead minnows and *Daphnia* all exceeded the aqueous solubility of C-1812 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 (calculated as 1.2 ppb) of C-1812.

In the daphnia study, 20% mortality occurred at the lowest concentration tested in replicate A, whereas replicate B showed no mortalities at the concentrations used in the study. Immobility was also seen in one daphnid in one of the two replicates of the diluent water control study and in one daphnid in one of the two replicates of the solvent control study. However, at the highest nominal concentration daphnids exhibited depressed activity but no immobility, while daphnids exposed to the intermediate concentration behaved normally. The notifier states the presence of undissolved material is known to have a physical effect on daphnids and this may explain the non-dose related findings, rather than chemical toxicity.

The above results indicate that C-1812 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-1812 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 such chemicals per annum to the sewer. This is a worse 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 notifier estimates, indicates the final concentration reached will be 0.8 ppb.

concentration in dispersion	=	50 $g.kg^{-1}$
rate of dilution in Kodak sewer	=	10^{-4}
concentration in sewer as it leaves Kodak	=	5 ppm
flow rate of Kodak sewer at exit point	=	4 x 10^5 L/day
flow rate (average) into Werribee	=	5 x 10^8 L/day
concentration reaching Werribee	=	4 ppb
rate of dilution in receiving waters	=	5 - 25 times
final concentration	=	0.8 - 0.2 ppb

This calculation assumes there will be no losses due to adsorption to sediment etc. The concentration is of the similar 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 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 either sediments or soil, and the expected exposure to natural organisms and bioaccumulation is likely to be low. Therefore, C-1812 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-1812 on human health have been reported. Animal tests indicate that C-1812 is of low toxic potential.

C-1812 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 dust proofing 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 and the public.

13. RECOMMENDATIONS

To minimise occupational exposure to C-1812, the following guidelines and precautions should be observed:

. storage of the powder and dispersion forms of C-1812 should be in robust, tightly sealed containers.

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

. engineering control procedures such as local exhaust ventilation should be employed in areas where C-1812 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 with 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 of the chemical, 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.

15. MATERIAL SAFETY DATA SHEET (MSDS)

The Material Safety Data Sheet for C-1812 (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.

16. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of C-1812 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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10. Mutagenicity Test on C-1812 in the Ames Salmonella/Microsome Reverse Mutation Assay, Hazelton Laboratories, Maryland, USA, Study No. 10726-0-401, 1989.

11. Mutagenicity Test on C-1812 In Vivo Mouse Micronucleus Assay, Hazelton Laboratories, Maryland, USA, Study No. 10726-0-455, 1989.

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

14. Australian Standard 1716-1991, "Respiratory Protective Devices", Standards Association of Australia Publ., Sydney, 1991.

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