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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

C-1867

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-1867

1. APPLICANT

Kodak Australasia Pty Ltd, 173 Elizabeth St, Coburg Vic 3058

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, C-1867, is considered to be non-hazardous. Therefore, the chemical name, CAS number, molecular formula, structural formula, methods of detection and determination and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Generic name: Alkyloxy substituted benzenamine

Shipping name: C-1867

Molecular weight: 389

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: clear, viscous amber liquid

Boiling Point: decomposes at 300°C prior to boiling

Glass-transition Temperature: -73°C

Density: 898.18 kg/m³ @ 20°C

Vapour Pressure: calculated to be
<1.61 x 10⁻⁴ kPa @ 23°C

Water Solubility: 1.3 x 10⁻³ µg/L at 24°C
(see below)

Partition Co-efficient (n-octanol/water) $\log K_{O/W}$:	estimated $\log K_{O/W} = 9.3$ (see below)
Flash Point:	149°C (Setaflash Closed Cup Apparatus)
Flammability Limits:	lower limit 0.294% (calculated) limit $\geq 1.91\%$ (calculated) on the flash point test, screening flammability and chemical structure, the chemical is considered to be combustible but not flammable, or pyrophoric
Combustion Products:	combustion will produce carbon dioxide, carbon monoxide, and oxides of nitrogen
Autoignition Temperature:	290°C
Explosive Properties:	not expected to be flammable based on the chemical structure
Reactivity/Stability:	based on chemical structure, the compound is not expected to be an oxidizer and there should be no conditions of instability or incompatibility
Particle size distribution:	not required as the chemical is a liquid
Comments on physico-chemical properties:	

Hydrolysis as a function of pH, adsorption/desorption and the dissociation constant could not be determined as the chemical is insoluble in water.

Kodak provided an estimated value of the partition coefficient according to the procedures outlined in OECD Test Guideline 117.

From this value, Kodak calculated the water solubility using the equation:

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

Due to the high partition coefficient strong adsorption to soils may be expected. The substance does not contain any functionalities likely to hydrolyze in the environmental pH range.

4. PURITY OF THE CHEMICAL

Degree of purity: ~90-97%

Toxic or hazardous impurity/impurities: none

The identities of the non-hazardous impurities have been exempted from publication in the Full Public and Summary Reports.

Additives/Adjuvants: none

5. INDUSTRIAL USE

C-1867 liquid will be imported into Australia for use in the manufacture of photographic film or paper. It will be imported at a volume of 85 kg in the first year and up to 385 kg per annum for the next 4 years.

6. OCCUPATIONAL EXPOSURE

C-1867 will be imported in preweighed units in sealed 20 L polyethylene drums which will be transported by road to Kodak Australasia, Coburg Vic. At Kodak, these units will be reweighed into units of 3-8 kg. Exposure to the liquid during the reweighing will be for approximately 10 min/unit and will involve up to 14 workers. Approximately 30 times a year 3 batches of gelatin dispersion will be produced. One C-1867 unit along with other ingredients will be added to a mix tank for each batch. The addition process will involve approximately 14 workers who

will be exposed for approximately 3 min/batch. The notifier states that these workers will wear overalls, industrial safety glasses, vinyl gloves and dust and particle masks during the addition. The immediate area will be under local exhaust ventilation.

The gelatin dispersion will be chilled and stored in covered cans for up to several weeks. When required the dispersion, as well as other addenda, will be manually added to melt tanks. The notifier states that workers will wear overalls, industrial safety glasses and vinyl gloves while handling the dispersion. The resulting dispersion will be pumped from the melt tank to closely controlled automated processing equipment where it will be incorporated into articles.

7. PUBLIC EXPOSURE

As C-1867 will be imported to Australia as a liquid in sealed drums and transported by road to the notifier, there is low potential for public exposure to the notified chemical during shipment and distribution.

The public should not be directly exposed to the chemical during manufacture. The dispersion will be manufactured in a sealed mix tank, stored in covered cans, and later pumped to closely controlled automated processing equipment for incorporation into articles as part of a multilayer coating. As the notified chemical is apparently nondiffusible and sandwiched between many layers of the photographic film, there is also low potential for public exposure from the finished product.

The notifier states that up to 10% of the aqueous dispersion could be released into the municipal sewer, resulting in a maximum concentration of 1.2 ppb. Chemical release from the automated processing equipment will be trapped by the Silver Recovery Department as "filter cake". Any chemical present here would be expected to be destroyed when the filter cake is subsequently smelted to regenerate silver. Public exposure from sewerage should be minimal due to the expected low concentrations.

8. ENVIRONMENTAL EXPOSURE

. **Release**

The chemical will be added to mix tanks approximately 30 times per year, in three-batch increments (90 batches per year) with other chemicals resulting in a dispersion. The dispersion will be chilled and stored in covered cans for up to several weeks. The dispersions will be taken from storage and added to melt tanks, where other chemicals will be added. The dispersion will then be pumped to closely-controlled automated processing equipment where the new chemical will be incorporated into articles. Once the chemical becomes part of the article, there will be no potential exposure to the new chemical, as the chemical will be under overcoat layers.

The company states there are no anticipated releases to the environment of the pure chemical. Approximately 10% of the aqueous dispersion containing C-1867 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.

Therefore, a batch of dispersion containing 6 kg of new chemical, with an expected waste of 10% would result in a 0.6 kg release to the sewer. This quantity will be diluted into 500 megalitres at Werribee, giving a concentration of approximately 1.2 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.

. **Fate**

C-1867 will mainly enter the environment when the dispersion containing the notified substance is discharged to the sewer. It would appear unlikely that C-1867 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-1867 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.

. **Bioaccumulation**

C-1867 is almost insoluble in water and is not readily biodegraded. Therefore, it may bioaccumulate. However, as the log K_{OW} value has been estimated as 9.3, these considerations taken together with the chemical's relatively large molecular size (3), would indicate that C-1867's bioaccumulation potential is likely to be low.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of C-1867

Test	Species	Outcome	Reference
Oral	Rat	LD ₅₀ : >5000 mg/kg	4
Dermal	Rat	LD ₅₀ : >18310 mg/kg	5
Skin	Rabbit	slight irritant	6
Eye	Rabbit	non-irritant	7
Skin	Guinea pig	non-sensitising	8

9.1.1 Oral Toxicity (4)

This study was conducted in accordance with OECD guideline No: 401 (9).

C-1867 was administered undiluted to 10 Spague Dawley rats (5 male and 5 female) by oral gavage, at a single dose of 5000 mg/kg. Clinical observations were made over a 14 day period.

One rat died during the course of this study (male on day 5). Macroscopic findings in this animal revealed a small thymus, brown discolouration of the non-glandular gastric mucosa, excessive amounts of black mucous in the small intestines, excessive amounts of brown mucous in the large intestines, black urine in the urinary bladder, a small submucosal haematoma in the urinary bladder, a small spleen, atrophy of the accessory sex organs, brown discolouration of the testes, black discolouration of the inguinal hair, and adipose tissue atrophy. Histopathology revealed thymic cortex atrophy; focal necrosis of the intestinal wall of the jejunum and the ileum; mucosal atrophy in the cecum; atrophy of the hepatocytes; atrophy of the accessory sex organs; atrophy of the splenic white pulp; and absence of adipose tissue from the abdominal organs.

All surviving rats were sacrificed on day 14, necropsy performed, and macroscopic findings recorded. Bodyweight gains of the surviving animals were unaffected by treatment and no clinical signs were noted. Upon necropsy these animals revealed no treatment-related macroscopic legions.

Results of this study indicate an acute oral LD₅₀ of >5000 mg/kg in rats of both sexes for C-1867.

9.1.2 Dermal Toxicity (5)

This study was conducted in accordance with OECD guideline No: 402 (10).

Undiluted C-1867 was applied to the clipped backs of Sprague Dawley rats (5/sex/dose) at either 2000 or 18,310 mg/kg (the later equivalent to ~20 ml/kg) and occluded for twenty-four hours. The dressing was subsequently removed and the test site washed with tap water. Clinical observations were made at 24 hours and once a day over a 14 day period. All rats were sacrificed on day 14 and necropsy performed.

No deaths, no signs of irritation or abnormal clinical signs were observed during the observation period. Bodyweight gains of the treated animals were unaffected by treatment. Necropsy on sacrificed animals revealed no significant macroscopic lesions.

Results of this study indicate an acute dermal LD₅₀ of >18,310 mg/kg in rats of both sexes for C-1867.

9.1.3 Skin Irritation (6)

This study was conducted in accordance with OECD guideline No: 404 (11).

A single dose of 0.5 g undiluted C-1867 was applied by occlusive application to the closely-clipped dorsa of 3 New Zealand White rabbits (male and/or female). Four hours later the dressings were removed and the test site washed with tap water. Skin reactions were assessed 1, 24, 48 and 72 hours, as well as 7 and 14 days after dressing removal. No clinical symptoms or mortality were observed in the animals during the 14 day observation period. Slight erythema was observed from 1 hour through to 48 hours in one animal, and up to 7 days in the other two animals. No signs of oedema, necrosis or eschar formation were noted during the test duration.

Results of this study indicate that C-1867 is a slight skin irritant in rabbits.

9.1.4 Eye Irritation (7)

This study was conducted in accordance with OECD guideline No: 405 (12).

A single dose of 0.1 ml of undiluted C-1867 was instilled in the conjunctival sac of one eye of each of 6 New Zealand White rabbits. Three of these animals had their eyes washed with distilled water immediately after instillation. The untreated eye of each animal served as the control. The eyes were examined immediately after instillation, and at 1, 24, 48 and 72 hours after instillation.

Slight erythema of the conjunctivae and nictitating membranes was observed 1 hour after administration in all animals (washed and unwashed eyes), however this effect had dissipated by 24 hours. No oedema, effects on the iris or corneal opacity were

apparent in any of the animals. No deaths occurred and no clinical symptoms were observed during the study.

The results of this study suggest that C-1867 is not an eye irritant in rabbits.

9.1.5 Skin Sensitisation (8)

This study was conducted using the Buelher Method in accordance with OECD guideline No: 406 (13). Test animals were BR Hartley guinea pigs. The vehicle was 70% acetone in distilled water.

Primary irritation study

Aliquots of C-1867 (0.5 ml at concentrations of 0, 0.39, 0.78, 1.56, 3.12, 6.25, 12.5, 25, 50 and 100 % in vehicle) were applied to the clipped backs of guinea pigs (3/dose). The test sites were occluded for 6 hours and then wiped free of excess material. Twenty four and 48 hours after application skin reactions were scored by the Draize method.

The maximal non-irritant concentration was determined to be 0.39% and the minimal irritant concentration determined to be 0.78%.

Induction

C-1867 at a concentration of 0.78% was applied to 10 animals (5 of each sex) once a week for three weeks using the method described above.

Challenge

Two weeks after the last induction dose, 0.39% C-1867 was applied to different sites on the backs of the same animals as well as 10 previously untreated animals (5 of each sex). Skin reactions were scored 24 and 48 hours after challenge application. No positive control substances were used in this study, however 1-chloro-2,4-dinitrobenzene had been used on the same strain of guinea pigs in the past year for study validation.

No signs of erythema or oedema were observed after challenge in any of the induced or non-induced animals. No body weight or other toxic effects were observed during the course of the study.

The results of this study suggest that C-1867 is not a skin sensitiser in guinea pigs using the Buehler Method.

9.2 Repeated Dose Toxicity (14)

This study was conducted in accordance with OECD guideline No: 407 (15).

C-1867 in corn oil was administered by gavage to groups of Sprague-Dawley rats (5/sex/dose) at doses of 0, 100, 300, or 1000 mg/kg/day, 5 days/week for 29 days (21 doses in total). Controls were given corn oil at volumes equal to the highest test group. At the conclusion of the study blood was collected for haematology and clinical chemistry, and the animals necropsied. Target organs were weighed and samples prepared for microscopic examination.

No mortality was observed during the study. No statistical differences were observed in body weights, although feed consumption and body weight decreases were reported in both male and female rats in the 1000 mg/kg group.

Treatment related clinical signs (appearing at day 10) included lethargy and unkempt hair coats in males and unkempt hair coats in females treated with the high dose. A number of animals (both sexes) treated with either the mid or low doses of C-1867 exhibited porphyrin nasal and lacrimal discharges, however this effect is believed to be due to non-specific stress. Other signs occurring in the lower doses as well as in the controls included diarrhoea and alopecia.

Haematological effects in males were limited to an apparent lowering of white blood cell counts (all doses), however differences were the result of an unusually high count in one of the control animals and were not dose-dependent. Haematological changes in females were also not dose-related, and included changes in red blood cell count, hematocrit, mean corpuscular haemoglobin concentration, monocyte counts and eosinophil count.

Clinical chemistries revealed a significant increase in mean total serum proteins in male rats treated with the high dose. Females given the same dose had significantly greater mean serum glucose, and decreased mean serum urea nitrogen and bilirubin. The decrease in urea was also apparent at the mid and low doses in the females, though these were not dose-related. The

significance of the elevated mean serum glucose levels is also questionable as the levels were within the normal range for this strain. Mean alkaline phosphatase was significantly increased in females at the mid dose only.

Statistically significant effects on organ weight were observed in absolute and relative liver weights (increase, both sexes, mid and high doses), and relative kidney and spleen weights (increase, female, high dose).

Gross pathology revealed no treatment-related effects in any of the groups.

Microscopic examination of the organs revealed changes in the liver only. Effects included hypertrophy of the hepatocytes (4 males, high dose; all males mid dose; all females, high and mid doses) and cytoplasmic basophilia in the hepatocytes (all males, high and mid doses; 2 females, high dose; 4 females, mid dose).

Based on the above results the target organ for toxicity is the liver.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (16)

This study was conducted in accordance with OECD guideline No: 471 (17).

C-1867 was used in a *Salmonella typhimurium* reverse mutation assay using the plate incorporation procedure in the test strains TA98, TA100, TA1535, TA1537 and TA1538, with or without metabolic activation.

All strains were tested with C-1867 at concentrations of 0, 10, 33.3, 66.7, 100, 333.3, 667, 1000, 3330, 6670 and 10000 µg/plate. The following reference mutagens were used as positive controls: sodium azide for TA 100 and TA 1535, - S9; 2-nitrofluorene for TA 98 and TA 1538, - S9; ICR-191 for TA 1537, - S9; and 2-aminoanthracene for all strains, + S9. All dose levels of C-1867, vehicle (ethanol) controls and positive controls were plated in triplicate.

Under the experimental conditions reported, C-1867 did not induce point mutations in any of the tester strains, with or without

metabolic activation. Therefore C-1867 is not considered to be mutagenic in this assay.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (18)

This study was conducted in accordance with OECD guideline No: 474 (19).

Three groups of ICR mice (5 of each sex/dose/harvest time) were given a single dose of either 500, 2500 or 5000 mg/kg C-1867 in corn oil (10 ml/kg) by gavage and sacrificed at 24, 48 and 72 hours after treatment. A satellite group was also treated with the high dose. Control animals were given corn oil alone and sacrificed at the same times. Positive controls were sacrificed at 24 hours after dosing with cyclophosphamide (80 mg/kg). Clinical signs and mortality was recorded during the test period. The satellite group served to replace any animals found dead from the high dose group.

Bone marrow was extracted from each mouse upon sacrifice and cells harvested for micronuclei analysis. Slides were prepared from cells of each animal. One thousand polychromatic erythrocytes (PCE) were scored per animal, and the number of micronucleated PCEs recorded. The frequency of micronucleated cells was expressed as percent of total PCEs scored per animal.

Two mice in the satellite group were found dead (1 male within 48 hours and 1 female after 72 hours). Clinical signs were seen from 24 to 72 hours in the high dose animals only. These animals were languid and had rough hair coats. The lower dose groups as well as the negative and positive controls remained normal in appearance.

No enhancement of micronuclei frequency was shown in treated animals at the above doses compared to the negative controls, at any of the harvest times. Cyclophosphamide produced a significant induction of micronuclei frequency.

C-1867 did not induce a significant increase in micronuclei in bone marrow polychromatic erythrocytes under the conditions of this study and is therefore considered to be negative in the micronucleus assay.

9.4 Overall Assessment of Toxicological Data

Animal studies have shown C-1867 to be of low toxicity by either the oral or dermal route (rat oral LD₅₀ >5000 mg/kg; rat dermal LD₅₀ >18310 mg/kg), slightly irritating but not sensitising to the skin; and non-irritating to the eyes. A 28-day repeated dose study in rats showed the main target organ for toxicity to be the liver.

Genotoxicity studies indicate that the chemical is not mutagenic towards *Salmonella typhimurium* and has no clastogenic effects *in vivo* in the mouse.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier has indicated that the test chemical will be imported at much less than 1 tonne per annum over the next five years. Therefore, in accordance with the Act, environmental effect studies are not required for the evaluation of this limited notification. However, the inhibition of microbial activity was investigated and the results are summarised below:

Test	Species	Result
Inhibition of Respiration	Activated sludge from a domestic waste water treatment plant	NOEC=100 mg/L

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

Owing to its very low solubility in water, the test material was added using a carrier solvent, acetone. Although this enabled the correct dosage to be delivered to each test beaker, white flakes of test substance were observed on the bottom of the beakers and in the test medium at the end of the test. To what extent this affected the results is not known. The above results indicate that C-1867 should not interfere with the necessary aerobic microbial action in sewage sludge.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The predicted maximum usage of C-1867 is 385 kg per annum. For one batch of emulsion, approximately 6 kg is used. If 10% (0.6 kg) goes to the sewer this will be diluted into 500 megalitres at

Werribee, giving a concentration of ~ 1.2 ppb. Further dilution (between 1:5 and 1:25) may occur when water is discharged into the receiving waters in a 1 km mixing zone around the outlets.

This calculation assumes there will be no losses due to adsorption to sediment etc. However, with a log K_{OW} value of 9.3, C-1867 is expected to readily adsorb to sediment and organic matter and should remain bound to the sediments located in the settling ponds at the Werribee complex (20). Consequently, its expected exposure to natural organisms and bioaccumulation is likely to be low and, together with its non interference with aerobic microbial action in sewage sludge, C-1867 is likely to present a low hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

C-1867 is a stable liquid at room temperature. It has low flammability, has no explosive characteristics, is not expected to be an oxidizer, and contains no hazardous impurities. Upon combustion it will form carbon dioxide, carbon monoxide, and oxides of nitrogen.

The toxicity profile of the notified chemical suggests skin contact and ingestion to be potential sources of human health effects. Skin effects are limited to slight irritancy and effects on the liver have been shown after repeated ingestion. No inhalational studies were conducted, however as the chemical has a low vapour pressure, inhalational exposure is expected to be minimal.

The chemical will be imported in small volumes, 85 to 385 kg/annum, and worker exposure will be limited to 10 minute periods a few times a year. Personal protective equipment will be worn by all workers during all handling operations involving exposure to C-1867 or other chemicals. Engineering controls such as local exhaust ventilation and enclosed processing equipment will further reduce any possible exposure.

Under normal use conditions, and with the appropriate engineering controls in place, C-1867 should not pose a significant risk to workers.

There is low potential for public exposure to the notified chemical. Therefore, there should be negligible risk to public safety when the chemical is used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to C-1867 the following guidelines and precautions should be observed:

If engineering controls and work practices are insufficient to reduce exposure to a safe level, the following protective equipment should be used:

- . goggles conforming to Australian Standards 1336 (21) and 1337 (22),
 - . vinyl gloves conforming to Australian Standard 2161 (23), and
 - . protective clothing conforming to Australian Standards 3765.1 (24) or 3765.2 (25).
- . Good work practices should be implemented to avoid splashing or spillages.
 - . Good personal hygiene practices, such as washing of hands prior to eating food, should be observed.
 - . A copy of the MSDS for products containing the notified chemical should be easily accessible to all employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for C-1867 was provided in Worksafe Australia format (26). 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-1867 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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