

File No: NA/65
Date: 21 July 1992

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

C-1813

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

C-1813

1. APPLICANTS

Kodak Australasia Pty Ltd, 173 Elizabeth Street, Coburg,
Victoria, 3058

2. IDENTITY OF THE CHEMICAL

Other name: C-1813

The nature and toxicological profile of the chemical indicate that it is likely to be non-hazardous. Therefore its chemical name, molecular formula and structural formula have been exempted from publication in the Full Public Report and Summary Report.

Molecular weight: 831.4

Method of detection and determination:

The notified chemical may be detected by high pressure liquid chromatography (HPLC).

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: orange solid

Melting point: 199.71°C

Vapour pressure: negligible

Water solubility: <0.1 mg/L at 25°C
(limit of detection)

Flash point:	not applicable
Flammability:	combustible
Combustion products:	hazardous combustion products include hydrochloric acid and oxides of carbon, nitrogen and sulphur
Autoignition temperature:	not applicable
Explosive potential:	not explosive
Reactivity/Stability:	incompatible with strong oxidisers; decomposes at temperatures > 235°C to hydrochloric acid, methane and oxides of carbon and nitrogen.
Particle size distribution:	not determined

Comments on physico-chemical properties

The water solubility value given is the detection limit of the methods used. The result is a limit value, caused by a relatively insensitive HPLC detection limit. This limit precludes an accurate assessment of the chemical's fate in the water compartment as a water solubility of <0.1 mg/L may not be low in environmental terms.

No data were provided for partition coefficient on the grounds that the test could not be performed due to low water solubility and lack of sufficiently sensitive analytical methods.

To maintain consistency with previous notifications, the notifier should provide partition coefficient and water solubility values if the level of importation exceeds 1 tonne per year.

No data were provided for hydrolysis on the grounds that the test could not be performed due to low water solubility and lack of sufficiently sensitive analytical methods. The notifier chemical

contains two amides and several other potentially hydrolysable functionalities but hydrolysis is expected to be slow under environmental conditions.

No data were provided for adsorption/desorption on the grounds that results are not measurable for chemicals with low water solubility. It should be noted that similar chemicals are known to adhere to surfaces of vessels in which the limit of water solubility was exceeded. Therefore, it is assumed the adsorption constant is high and the notified chemical is likely to adsorb onto solid materials.

No data were provided for dissociation constant on the grounds that results are not measurable for chemicals with low water solubility. The notified chemical contains several amino functionalities but it is unclear whether these are acidic or basic.

No data were provided for specific density on the grounds of negligible environmental exposure.

No data were provided for vapour pressure on the grounds of negligible environmental exposure. High molecular weight and complex functionality indicate vapour pressure is likely to be low.

4. PURITY OF THE CHEMICAL

Degree of purity: 98.7%

Impurities: Analysis indicated the presence of three impurities which have not been identified. Each is present in quantities of <0.6%, totaling approximately 1.3%.

5. INDUSTRIAL USES

The notified chemical is to be used in the manufacture of photographic material. It will be imported into Australia in quantities of <125 kg/annum.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported and stored in sealed shipping containers. Exposure during transport and storage will be nil unless accidents occur.

The notified chemical will be imported in preweighed quantities. Workers involved in the manufacture of photographic materials will add the notified chemical to a mix tank to form a dispersion. The dispersion will be stored and other ingredients added at the time of manufacture. During the handling of the notified chemical, the most likely occupational exposure will be inhalational or dermal exposure to the dust. Once incorporated into the film or paper the chemical will be coated and no additional worker exposure will take place. Workers adding preweighed dry chemical to the initial mix will wear protective clothing, safety glasses, gloves and masks to minimise exposure. Exhaust ventilation will minimise airborne concentrations. Protective clothing, masks, goggles and gloves will be worn when handling the dispersions.

7. PUBLIC EXPOSURE

The notified chemical will be imported in sealed shipping containers. Therefore significant risk of public exposure is not expected during transport.

Under the stated conditions of use, public exposure to the notified chemical will be minimal due to minimal release of the chemical to the environment, and the overcoating of the chemical after incorporation into photographic film or paper. Approximately 10% of the dispersion containing the notified chemical could be released to the municipal sewer, with a further 10% being released from the automated processing equipment. The municipal sewer flow will be routed for secondary treatment operated by the Melbourne Metropolitan Board, with subsequent dilutions resulting in a final concentration of 2 ppb. Containers of the imported chemical and plastic bags containing residual dispersion, and <1% of waste will be sent to a secured landfill.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier states that there are no anticipated releases to the environment of the pure chemical. Approximately 10% (to be confirmed) of the aqueous dispersion containing the notified chemical could be released to the municipal sewer. Further losses of about 10% will be encountered from the incorporation of the notified chemical to the film or paper. However, this waste will be routed through the silver recovery plant and from its physico-chemical properties the notified chemical is likely to be adsorbed to solids from which silver (~10%) is recovered at 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 will be routed for secondary treatment at the Werribee treatment facility. Less than 1% of wastes may be sent a secured landfill.

Fate

The notified chemical will mainly enter the environment when the dispersion is discharged to the sewer. No biodegradation studies were provided by the notifier. However, based on the biodegradation studies of similar previously notified chemicals, this notified chemical is unlikely to biodegrade 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 (1). 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 the notified chemical 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

The notified chemical has low water solubility and is not readily biodegraded. Therefore, it may bioaccumulate. However, the high molecular weight and relatively large molecular size may preclude this (2). Had the notifier provided a log $P_{o/w}$ value, the Department of the Arts, Sports, the Environment and Territories

(DASET) would have been able to define the bioaccumulation potential of the notified chemical more accurately, eg. a log $P_{o/w}$ greater than 6 would indicate a reduced bioaccumulation potential (2).

The possibility of soil accumulation needs consideration. However, the notified chemical 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

The *Industrial Chemicals (Notification and Assessment) Act .2989* does not require toxicology data to be submitted on chemicals imported in quantities of < 1 tonne / year. Nevertheless some tests have been conducted on the notified chemical and were submitted as part of the notification statement.

OECD Test guidelines 401 (4).

Five male and five female CD (SD) BR rats received single oral doses of 5000 mg/kg of the notified chemical by gavage as a

Test	Species	Outcome	Ref
Oral	Rat	>5000mg/kg	(3)
Dermal	Rat	>2000mg/kg	(5)
Skin irritation	Rabbit	non-irritant	(7)
Eye irritation	Rabbit	slightly irritant	(9)
Skin sensitisation	Guinea Pig	non sensitising	(11)

9.1.1 Oral Toxicity

20% suspension in corn oil. Animals were observed for a 14 day period.

Orange coloured diarrhoea was noted in two females on the day of dosing and discoloured faeces in all animals 24 hours after dosing. Diarrhoea was possibly caused by the vehicle and the discolouration by the notified chemical. No other clinical signs or symptoms were noted. No deaths occurred. No abnormal findings were noted at gross examination at necropsy.

The oral LD₅₀ in rats was concluded to be >5000mg/kg.

9.1.2 Dermal Toxicity OECD Test Guidelines 402 (6)

A single dose of 2000mg/kg of the notified chemical on a fibre pad was applied to a clipped dorsal area of each of five male and five female CD(SD) BR rats. The application was held together by occlusive wrapping for a 24 hour period. On removal of the wrapping, the site was cleaned with acetone. Animals were observed for 14 days.

No clinical signs of toxicity were noted. Weight gain was normal and no abnormalities were reported at necropsy.

Dermal LD₅₀ in rats was > 2000mg/kg in this study.

9.1.3 Skin Irritation OECD Guideline 404 (8)

Half a gram of the notified chemical was applied to a clipped area of skin of each of three New Zealand white rabbits and held in place under an occlusive wrap for four hours (7). Animals were observed for 14 days.

No erythema or oedema at the application site was noted at any time interval. Animals gained weight and no other adverse effects were noted.

The notified chemical was concluded to be non irritating to the skin in this test.

9.1.4 Eye Irritation OECD Guidelines #405 (10).

Six New Zealand White rabbits received a single dose of 50 mg of the notified chemical in the conjunctival sac of one eye (9). The other untreated eye served as the control. In three animals, the eye was washed immediately with distilled water. In the remaining three animals the eyes were unwashed.

Observations were made immediately and at 12, 24, 48 and 72 hours after installation of the chemical. Fluorescein examination was carried out at 24 hours.

At one hour after instillation, all eyes (washed and unwashed) exhibited mild erythema. After 24 hours two unwashed eyes still showed erythema, all washed eyes had cleared. No corneal effects were reported. All three washed eyes were normal by 24 hours,

unwashed eyes were normal by 48 hours.

The notified chemical appears to be slightly irritating to the eye.

9.1.4 Skin Sensitisation (11)

The notified chemical was applied to the clipped skin area of five males and five female HABR Hartley guinea pigs three times in a three week period. Patches were left in place for six hours. Two weeks later, animals were challenged by application of the notified chemical to a clipped new site on the opposite side of the animal. Five male and five female untreated animals served as a control group. Animals were observed at 24 and 48 hours after challenge. No positive control group was included, although historical data from the previous 12 months was available with known sensitisers in this strain of guinea pig.

No signs of erythema or oedema were noted in any of the animals. The notified chemical was concluded to be a non-sensitiser in this test, although the lack of a positive control weakens this conclusion.

9.2 Genotoxicity (12)

The notified chemical was assayed for mutagenicity against five strains of *Salmonella typhimurium*. At concentrations of 333 - 1000 pg/plate, with and without metabolic activation, it was incubated with strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538 for 48 hours and the number of revertant strains counted. The vehicle, DMSO, served as negative control. The positive controls used were:

With metabolic 2 aminoanthracene, 2.5 pg/plate, all strains activation

Without S9 metabolic activation	2-nitrofluorene, 1.0 pg/plate	TA 98 TA1535
	sodium azide, 2.0 pg/plate	TA 100 TA 1535
	ICR - 191, 2.0 pg/plate	TA 100, TA 1535 TA 1537

No increases in revertant colony counts were reported with any concentration of the test substance, with or without metabolic activation. All positive controls produced increases.

The notified chemical was not mutagenic towards *S. typhimurium* in this test.

9.2 Overall Assessment of Toxicological Data

The notified chemical was found to have low acute toxicity in rats by oral and dermal administration. It was non-irritating to the skin but slightly irritating to the eye in rabbits. It is not a skin sensitiser in guinea pigs. It was not mutagenic towards *Salmonella typhimurium* *in vitro*.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notified chemical being a low volume chemical, it is not a requirement under the Act that environmental effects studies be submitted for assessment.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Up to 25 kg (to be confirmed by notifier) of the notified chemical may be discharged to sewage treatment works per annum where it is likely to adsorb to sludge or soil. It should be noted that the notified chemical will be one of a number of new chemicals that will be used during the one product run, resulting in the notifier releasing approximately 3.6 tonne of such chemicals per annum to the sewer. This is a worst case assuming 20% discharged to the sewer.

As noted above, the dispersion will be made up about 25 times per year and assuming equal lots, about 1 kg per batch will be discharged. The following "worst case" calculation, using the notifier's estimates, indicates that the final concentration reached will be 0.6 ppb.

rate of dilution in the notifier's sewer	$=10^{-4}$
concentration in the sewer as it leaves the notifier's premise	$= 4 \text{ ppm}$
flow rate of notifier's sewer at exit point	$= 4 \times 10^5$ L/day
flow rate (average) into Werribee	$= 5 \times 10^8$ L/day
concentration reaching Werribee	$= 3.2 \text{ ppb}$
rate of dilution in receiving waters	5 - 25 times
final concentration	0.6 - 0.1 ppb

This calculation assumes there will be no losses due to adsorption to sediment etc. In line with previous notifications of similar chemicals, the notified chemical 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, the notified chemical is likely to present a low hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY

The notified chemical is non-irritating to the skin, however, it is slightly irritating to the eye and may be reasonably assumed to be irritating to the respiratory tract. No information on particle size was available.

In the absence of information on particle size, respirators should be worn when the powder is handled and engineering controls such as local exhaust ventilation should be implemented to minimise dust. As the notified chemical has been found to be slightly irritating to the eye, eye protection should also been worn.

13. RECOMENDATIONS FOR THE CONTROL OF PUBLIC, WORKER AND ENVIRONMENTAL EXPOSURE

To minimise public, worker and environmental exposure to the notified chemical the following guidelines and precautions should be observed:

- workers handling the powder should wear safety glasses with side shields conforming to Australia Standard 1337 - 1984 (13) and dust masks conforming to Australian Standard 1715-1991 (14);
- local exhaust ventilation should be used when the notified chemical and products containing it are in use;
- avoid generation of a dust cloud;
- MSDS for the notified chemical and products
- containing it, should be available to workers.
- if repeated exposure to the notified chemical occurs, protective clothing and gloves should be worn;
- the notifier in conjunction with the Melbourne Water, should continue to look at ways of minimising the amount of chemical being discharged to the sewer.

14. MATERIAL SAFETY DATA SHEET(S)

The Material Safety Data Sheet (MSDS) for the notified chemical (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 the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. The partition coefficient and

water solubility should be defined more accurately if the level of importation rises above one tonne.

16. **REFERENCES**

- (1) The Department of the Arts, Sport, the Environment and Territories, "Australian Sewage Profile", 1988.
- (2) Connell, D.W., "Bioaccumulation of Xenobiotic Compounds", CRC Press, 1990.
- (3) Acute Oral Toxicity of C-1813 (TX-89-98). Data on File, Eastman Kodak Company, Rochester, NY, 14652 - 3615, USA.
- (4) OECD: Guidelines for the Testing of Chemicals #471 Acute Oral Toxicity.
- (5) Acute Dermal Toxicity of C-1813 (TX-89-99). Data on file, Eastman Kodak Company, Rochester, NY 14652 - 3615, USA.
- (6) OECD: Guidelines for the Testing of Chemicals #402. Acute Dermal Toxicity.
- (7) Acute Skin initiation of C-1813 (TX-89-100). Data on File, Eastman Kodak Company, Rochester, NY 14652 - 3615, USA.
- (8) OECD: Guidelines for the Testing of Chemicals: No 404 Acute Skin Initiation.
- (9) Acute Eye initiation of C-1813 (TX-89-103). Data on File Eastman - Kodak Company, Rochester, NY 14652 - 3615, USA.
- (10) OECD guidelines for the Testing of Chemicals. # 405 Acute Eye Initiation.
- (11) Skin sensitization (Buehler Method) of C-1813 (TX - 89 -101) Data on file: Eastman Kodak Company, Rochester, NY 14652 - 3615, USA.
- (12) Mutagenicity Test on EK 89-D014, C-1813 on the Salmonella / Mammalian - Microsome. Reverse Mutation Assay (Ames Test) with confirmatory Assay. BLA Study No. 12080-0-401R. Data on File: Eastman Kodak Company, Rochester, NY, 14652 - 3165, USA

- (13) Australian Standard 1337-1984 *Eye Protectors for Industrial Applications*, Standards Association of Australia, Sydney 1984.
- (14) Australian Standard 1715-1992 *Selection, Use and Maintenance of Respiratory Protective Devices*, Standards Association of Australia, Sydney 1991
- (15) Guidance Note for Completion of a Material Safety Data Sheet. [NOHSC : 3001 (1991)], 3rd Edition, October 1991.