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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

C-398

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

C-398

1. APPLICANT

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

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, C-398 is considered to be non-hazardous. Therefore, the chemical name, CAS number, molecular and structural formulae, exact composition, density, water solubility, and reaction products have been exempted from publication in the Full Public Report and the Summary Report.

Trade name: C-398 (shipping name)

Molecular weight: 526.2 g

Method of detection and determination:

Detection can be made by UV-VIS absorption spectroscopy and X-Ray diffraction.

Spectral data:

UV-VIS spectra was measured and a single peak observed.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	White solid
Odour:	none mentioned
Melting Point:	> 300°C
Vapour Pressure:	Not available

Fat Solubility: Not available

Partition Co-efficient: $P_{o/w} < 0.002$ (estimated)
(n-octanol/water)

Hydrolysis as a function of pH: Not available

Adsorption/Desorption: Not available

Dissociation Constant: Not available

Flash Point: Not available

Flammability Limits:

The material is considered to be combustible but not highly flammable, nor pyrophoric.

Decomposition Temperature and Products: Not available

Autoignition Temperature: Not available

Explosive Properties:

The chemical was not found to be explosive.

Reactivity/Stability:

C-398 is not an oxidizer. It is not flammable in contact with moisture or damp air and does not produce gas or flame on contact with water.

The substance is considered to be stable at room temperature. The only condition thought to lead to instability is the loss of water of hydration upon heating.

Particle Size Distribution: Not available

Comments on Physico-chemical Properties

Vapour pressure, hydrolysis as a function of pH, adsorption/desorption, dissociation constant, particle size, flash point and autoignition temperature were not provided due to the expected "negligible occupational and environmental exposure".

The partition coefficient could not be measured by the conventional shake flask method (OECD TG 107) (1). This was due to the very low solubility of the chemical in n-octanol (estimated to be in the low parts per billion range) and the dissociation of the chemical in water.

The dissociation constant was not determined, but the chemical is known to dissociate in water.

C-398's low partition coefficient and high water solubility indicate that its adsorption potential is likely to be low.

The substance's relatively high molecular weight and existence in salt form indicate that it is unlikely to volatilise under environmental conditions.

As only 2 kg of the C-398 is to be imported and used annually these omissions are acceptable.

4. PURITY OF THE CHEMICAL

Degree of purity: 96.5% (by gravimetry)
allowed range : 93.6 - 99.2 %

Impurities: none detected

5. INDUSTRIAL USES

The C-398 will be used in the manufacture of photographic film and paper. Less than 2 kg is to be imported annually, and the substance will not be manufactured in Australia. No work related injury or disease or other occupational hazards associated with C-398 are known to the submitter.

6. OCCUPATIONAL EXPOSURE

It is expected that a total of 23 people will be working with C-398 all at a single site in Australia. Six operators will be handling the dry material and a further 17 shall be working with an emulsion containing C-398.

7. PUBLIC EXPOSURE

Less than 2 kg of the notified substance is to be imported annually into Australia and therefore public exposure is expected to be extremely low. Transport is to occur in sealed containers, and prior to the opening of these no exposure is likely to occur.

The chemical is to be used by the notifier at only one site. After it has been incorporated into the article no further potential for exposure is thought to exist.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Approximately 25 times per year the chemical will be reweighed in an Australian laboratory, then added to a mixing tank containing water. The solution will be stored in closed plastic bottles for up to several weeks. The solution will be taken from storage and along with other addenda, will be added to a photographic emulsion. The photographic emulsion will then be pumped to closely controlled automated processing 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 that there are no anticipated releases to the environment of the pure chemical. Less than 1% of the emulsion and a further 10% of the melt containing the new chemical will be released to the municipal sewer. However, this waste is routed through the silver recovery plant in Port Kembla and may be absorbed to solids from which silver (about 10%) is recovered and the remainder incinerated. The company is presently undertaking analytical testing of the initial effluent, the recovered cake and the filtrate to confirm how much C-398 and other recently notified substances will bind to solids during this recovery process. Whether the soluble C-398 would adsorb is unclear. 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-398 will enter the environment mainly when waste is discharged to the sewer. No biodegradation studies were provided by the

notifier (these are not part of the small volume chemicals requirements) and the biodegradation of C-398 remains unclear. 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). The most likely fate of C-398 would appear to be dissociation in water. It is unclear whether the dissociation complex is likely to adsorb to suspended matter and then settle out over land or into lagoon sludge, as sewage inflow passes through the filtration systems at Werribee. However, the environmental exposure of C-398 is likely to be very low as only about 0.2 kg per annum is likely to find its way to Werribee.

Bioaccumulation

C-398 is unlikely to bioaccumulate due to its high water solubility and low partition coefficient.

8.3 Exposure Level

Volume and Use

C-398 will be imported at less than 2 kg per annum.

Manufacture or reformulation of the chemical will not occur in Australia. Therefore, there will not be any environmental release of the chemical via this route.

The use of C-398 will occur at only one site, in Melbourne. The chemical will be used in the manufacture of photographic film/paper.

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicology data is required under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) for chemicals to be imported in quantities of < 1 tonne/year. These studies have been carried out and reported.:

9.1 Acute Toxicity

1. Summary of acute toxicity of C-398.

Test	Species	Outcome	REF
Oral	Rat	1250 < LD_{50} < 2500 mg/kg	3
Irritation	Rabbit	non irritant	4
Irritation	Rabbit	slight irritant	5

9.1.1 Oral Toxicity (3)

A limited study of the acute oral toxicity of C-398 was made. Male and female rats (strain CD (SD)BR VAF/Plus) were treated by gavage with 625, 1250, 2500, or 5000 mg/kg of the test material in a vehicle of distilled water. One animal of each sex was assigned to each dose. No control animals were used.

Both animals treated with 5000 mg/kg died within 3 hours of treatment and both animals treated with 2500 mg/kg died the day after treatment. Animals treated with the lower two doses survived to necropsy 14 days post-treatment. Abnormal clinical signs in all animals were limited to slight weakness and black diarrhoea for up to one day.

Histological and gross pathological changes were observed in all animals except for the male treated with 1250 mg/kg. At the lowest dose (625 mg/kg) moderate pallor of the cortex of the kidney was observed and in the male moderate atrophy of the accessory sex glands observed. Both animals showed moderate increases in the cytoplasmic basophilia of the epithelium and dilatation of the lumena of the proximal convoluted tubules. Diffuse fibrosis of the parietal surfaces of the Bowmans capsules was evident and focal accumulation of chronic inflammation cells was observed in the interstitial renal tissue. The animals at this dose continued to gain weight normally.
treated with higher doses exhibited increasingly severe symptoms. At 5000 mg/kg these included diffuse necrosis, excessive mucous accumulation and haemorrhage in the glandular gastric mucosa of the male, and oedema and diffuse necrosis into the gastric mucosa of the female. Blackening of the contents of the caecum, colon, and rectum, and of the inguinal hair was present. The animals also presented with diffuse necrosis of the epithelium of the proximal convoluted renal tubules and granular casts in the lumena of the tubules. The probable cause of death was diffuse necrosis of the proximal convoluted renal tubules evidenced by necrosis, the accumulation of chronic inflammatory cells in the renal interstitial tissue, and histological changes suggestive of epithelial regeneration, C-398 is toxic to the kidneys. C-398 is also irritating to the glandular gastric mucosa as evidenced by necrosis and haemorrhage. The LD_{50} was concluded to lie between 1250 and 2500 mg/kg and the substance was classified as harmful according to Worksafe guide-lines for acute toxicity (6).

9.1.2 Dermal Toxicity (4)

A limited acute dermal study was performed using 3 Hra strain New Zealand White young adult rabbits of unspecified sex. No control animals were used and no vehicle was required apart from the test material being moistened with a little water. A single dose of 0.5 g of the substance was placed in contact with the clipped dorsal skin of each animal using a fibre pad, and an occlusive wrap was used to hold the material in place for four hours. At the end of this period C-398 was removed with running water. Clinical symptoms were observed at the end of 1, 24, 48, and 72 hours and again at 7 and 14 days after removal of the patch.

No irritant response was reported at any time during the study. No toxic effects via percutaneous absorption were evident and all animals gained weight normally.

C-398 is therefore non-toxic via the dermal route of exposure.

9.1.3 Eye Irritation (5)

0.1 g of C-398 was instilled into the conjunctival sac of one eye of each of 6 non-sexed New Zealand White rabbits of the Hra strain. Three of the eyes were washed immediately with running distilled water and the others were left unirrigated. Immediate washing of the eye was palliative. In these eyes symptoms were limited to slight erythema of the conjunctival and nictitating membranes one hour after treatment. Corneal or adnexal injury were not evident as determined from the fluoroscein dye test. All 3 washed eyes appeared as normal after 24 hours.

Signs of irritation in the un-washed eye included slight to moderate erythema and oedema of the conjunctival and nictitating membranes, and slight erythema of the lids. Slight to moderate discharges were reported one hour after exposure. No corneal or adnexal staining occurred with fluoroscein dye 24 hours after treatment, indicating the absence of scarring of these tissues. At 48 hours, 2 of the 3 treated eyes appeared normal, but slight erythema of the adnexal was seen in the 3rd eye. All symptoms had disappeared by 72 hours.

C-398 was concluded to be slightly irritating to the eye of the rabbit under the conditions of this test.

9.2 Overall Assessment of Toxicological Data

Only acute toxicity data was available for the chemical C-398. The data shows C-398 to be a chemical of low oral toxicity to rats with an LD_{50} between 1250 and 2500 mg/kg. It is slightly irritating to the eye but not a dermal irritant in rabbits. The compound is irritating to the intestinal tract and toxic to the kidneys of rats.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Environmental effect studies were not carried out which is acceptable under the Act for chemicals to be imported in quantities < 1 tonne/year.

11. ASSESSMENT OF ENVIRONMENTAL HAZARDS

It should be noted that C-398 will be a very minor component of a number of new chemicals that will be used during the one product run, resulting in Kodak releasing a total of approximately 3.6 tonnes of new chemical substances per annum to the sewer.

The usage of C-398 is < 2 kg per annum. For 25 batches of solution per year, approximately 80 g of C-398 is used per batch in a worst case situation. If 11% (8.8 g) goes to the sewer this will be diluted into 500 ML at Werribee, giving a concentration of ~0.02 ppb. Further dilution (between 1:5 and 1:25) will 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. In line with the notifications of similar chemicals the substance is likely to remain with the Werribee sewerage complex, most likely in solution but possibly adsorbed to either sediment or soil, and the expected exposure to natural organisms and bioaccumulation is likely to be low. Therefore, C-398 is likely to present a low hazard to the environment.

Communications with Kodak and Melbourne Water, including a site visit, have disclosed that Kodak has initiated an active program aimed at identifying and reducing the volume of these discharged chemicals. This includes a renegotiation with Melbourne Water regarding the amount of treated effluent allowed to be discharged.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY

Provided that good hygiene is adopted the hazards associated with C-398 appear to be minimal and occupational and public exposure is not expected.

13. RECOMMENDATIONS

To minimise occupational exposure to C-398 the following guidelines and precautions should be observed:

- The workplace should be well ventilated and local exhaust ventilation should be used in areas where the dry solid is to be handled;

- Suitable personal protective equipment complying with Australian Standards should be used where exposure to the substance is possible:

  - protective clothing (AS 3765.1) - *Clothing for Protection against Hazardous Chemicals* (7),

  - Safety Glasses (AS 1337) - *Eye Protectors for Industrial Applications* (8),

  - Disposable impervious gloves (AS 2161) - *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves* (9),

  - Particulate filter respirator (AS 1716) - *Respiratory Protective Devices* (10) for protection against the substance in solid form,

  A copy of the MSDS should be easily accessible to all users of this product.

- It isrecommended that the notifier, in conjunction with Melbourne Water, continue to look at ways of minimising the amount of C-398 and associated chemicals being discharged into the sewerage system.

14. MATERIAL SAFETY DATA SHEET(S)

The Material Safety Data Sheet (MSDS) for C-398 (Attachment 1) was provided in Worksafe Australia format (11). This MSDS was provided by Kodak 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.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of C-398 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

1. OECD Guidelines for testing of Chemicals; Section 1: Physical- Chemical Properties: TG 107. Organization for Economic Co-operation and Development, Switzerland 1987.

2. "Australian Sewage Profile", Department of the Arts, Sport, Environment and Territories internal report, 1988.

3. C-398 acute oral toxicity study in the rat; Project No. 90-0138 (TX-91-57) KP Shepard, Toxicological Sciences Laboratory, Health and Environment Laboratories, Eastman Kodak Company, New York, 1991.

4. C-398 acute dermal irritation study in the rabbit; Project No. 90-0138 (TX-91-17), KP Shepard, Toxicological Sciences Laboratory, Health and Environment Laboratories, Eastman Kodak Company, New York, 1991.

5. C-398 acute eye irritation study in the rabbit; Project No. 90-0138 (TX-91-17), KP Shepard, Toxicological Sciences Laboratory, Health and Environment Laboratories, Eastman Kodak Company, New York, 1991.

6. Guidance note for determining and classifying a hazardous substance NOHSC: 3011 (1991), National Occupational Health and Safety Commission, Australian Government Publishing Service, Canberra, June 1991.

7. Australian Standard 3765.1 - *Clothing for Protection against Hazardous Chemicals; Part 1,: Protection Against General or Specific Chemicals*; Standards Association of Australia Publ; Sydney, 1990.

8. Australian Standard 1337 - *Eye Protectors for Industrial Applications*; Standards Association of Australia Publ; Sydney, 1984.

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

10. Australian Standard 1716 - *Respiratory Protective Devices*, Standards Association of Australia Publ; Sydney, 1991.

11. Guidance Note for Completion of a Material Safety Data Sheet [NOHSC:3001(1991)] Australian Government Publishing Service, Canberra, 1991.